California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Contact Person: Jan E. Perez (916) 445-5014

LEGISLATION & REGULATION COMMITTEE

April 7, 2005
Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento, CA 95814
9:30 a.m. – 1:00 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 48 hours prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Board members who are not on the committee may be attending and may comment on the committee's agenda.

A.	**Call to Order**	**9:30 a.m.**
B.	**Consideration of Bills of Interest to the Board of Pharmacy.**	
C.	**Consideration of Proposed Initiatives of Interest to the Board of Pharmacy.**	
D.	**Regulation Update.**	
E.	**Review of the Committee's Strategic Plan Update.**	
F.	**Comments from the Public on Items Not on the Agenda.**	
G.	**Setting Next Meeting Date**	
Adjournment		**1:00 p.m.**

State of California Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee Date: March 25, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Regulations and Legislation Update

Regulation Calendar

The board submitted its 2005 rulemaking calendar to the Office of Administrative Law (OAL) in January 2005. The board anticipates sending its Compounding rulemaking package to OAL for review and approval in April 2005, and noticing Pharmaceutical Practice regulations in July 2005, with Delivery of Prescriptions noticing to follow in October 2005. Attachment 1.

Legislation

Board Sponsored Legislation

AB 595 (Negrete McLeod) Pharmacy: compounding of prescription drugs.
This bill is sponsored by the board to define "compounding" and to provide direction for regulation that will follow later this year. The board approved draft legislation at its January 2005 meeting.

Bills of Interest

AB 21 (Levine) Pharmacists: contraceptive devices.
Status: Assembly Health Committee - Hearing April 5, 2005

AB 71 (Chan) Pharmaceuticals: adverse drug reactions: Office of Ca. Drug Safety Watch.
Status: Assembly Health Committee - Hearing April 12, 2005

AB 72 (Frommer) Prescription drugs: manufacturer reporting requirement.
Status: Assembly Health Committee - Hearing April 12, 2005

AB 73 (Frommer) Prescription drugs: importation: procurement.
Status: Assembly Health Committee - Hearing April 12, 2005

AB 74 (Gordon) California Rx Prescription Drug Hotline.
Status: Assembly Health Committee - Hearing April 12, 2005

AB 75 (Frommer) Pharmaceutical assistance program.
Status: Assembly Health Committee - Hearing April 12, 2005

AB 76 (Frommer) Office of Pharmaceutical Purchasing.
Status: Assembly Health Committee - Hearing April 12, 2005

AB 78 (Pavley) Pharmacy benefits management.
Status: Assembly Health Committee - Hearing April 12, 2005

AB 225 (Negrete McLeod) Electronic prescription information.
Status: Assembly Health Committee - Hearing April 5, 2005

AB 283 (Koretz) Pseudoephedrine: retail sale.
Status: Assembly Public Safety Committee

AB 288 (Mountjoy) Pharmacies: prescription containers: labels.
Status: Assembly Health Committee

AB 497 (Negrete McLeod) Drug wholesalers and manufacturers: licensure exemption.
Status: Assembly Health Committee - Hearing April 12, 2005

AB 657 (Karnette) Pharmacies: prescription containers.
Status: Assembly Health Committee - Hearing April 12, 2005

AB 522 (Plescia) Automated drug delivery system.
Status: Assembly Health Committee - Hearing April 5, 2005

AB 896 (Matthews) Clinical laboratories.
Status: Assembly Business and Professions Committee

AB 1370 (Matthews) Clinical laboratory director: pharmacists.
Status: Status: Assembly Business and Professions Committee

SB 19 (Ortiz) California Rx Program.
Status: Senate Health Committee - Hearing April 13, 2005

SB 152 (Speier) Pseudoephedrine.
Status: Status: Senate Business, Professions, and Economic Development Committee

SB 380 (Alquist) Drugs: adverse event reporting.
Status: Senate Health Committee - Hearing March 30, 2005

SB 401 (Ortiz) Medical information: pharmacies: marketing.
Status: Senate Health Committee - Hearing April 6, 2005

SB 592 (Aanestad) Acute care hospitals: inpatient pharmacy technician services.
Status: Senate Business, Professions, and Economic Development Committee

SB 644 (Ortiz) Dispensing of prescriptions.
Status: Senate Business, Professions, and Economic Development Committee - Hearing April 11, 2005

SB 734 (Torlakson) Controlled substances.
Status: Senate Health Committee - Hearing April 6, 2005

Initiative Assessment

In February the Legislative Analyst Office requested the board review three proposed initiatives. The three are listed below. A copy of the analysis follows.

SA05RF0051 - Prescription Drugs. Initiative Statute.
Status: In circulation

SA05RF0052 - Prescription Drugs Act. Initiative Statute.
Status: In circulation

SA05RF0065 - California State Pharmacy Assistance Program (CAL Rx)
Status: Attorney General awaiting preparation of title and summary

Pending Regulations

Omnibus Rulemaking 2004 – A number of modifications were approved by the board during the January 19, 2005 meeting and released for 15-day notice comment period – no comments were received. The rulemaking file is being compiled by staff and will be submitted to the Administration for review before the board meeting.

Section 1706.2. – Abandonment of Application Files.
Summary: This change consolidates provisions related to the abandonment of applications.
Status: Rulemaking Notice Published February 2, 2005.

Section 1712. - Use of Pharmacist Identifiers.
Summary: Senate Bill 1913 (Chapter 695, Statutes of 2004) amended Business and Professions Code section 4115 to allow the use of systems approved by board regulations and this regulation implements that provision.
Status: Rulemaking Notice Published February 2, 2005.

Section 1715. - Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.
Summary: Existing versions of the pharmacy self assessment forms require updating to reflect numerous recent changes to pharmacy law.
Status: Rulemaking Notice Published February 2, 2005.

Section 1715.5. - Implementation of Electronic Monitoring of Schedule II Prescriptions.
Summary: This section is repealed because Senate Bill 151 (Chapter 406, Statutes of 2003) amended section 11165 of the Health and Safety Code to specify how pharmacies must report the dispensing of controlled substances.
Status: Rulemaking Notice Published February 2, 2005.

Section 1717. - Pharmacy Practice.
Summary: This section is amended to make technical corrections.
Status: Rulemaking Notice Published February 2, 2005.

Section 1719. - Recognized Schools of Pharmacy.
Summary: This change will allow the board to issue intern pharmacist licenses to students in pharmacy schools with candidate status and for the board to allow graduates of pharmacy schools with candidate status to sit for the licensing examinations. Schools with candidate status are at the penultimate step of accreditation, but final accreditation can occur after students have been enrolled and need to obtain internship hours or to be qualified to take the licensure examinations.
Status: Rulemaking Notice Published February 2, 2005.

Section 1720. - Application for Pharmacist Examination and Licensure.
Summary: These changes are made to conform to the examination structure specified in Senate Bill 361 (Chapter 539, Statutes of 2003) and to delete provisions related to application abandonment that are relocated to section 1706.2.
Status: Rulemaking Notice Published February 2, 2005.

Section 1720.1. - Graduates of Foreign Pharmacy Schools.
Summary: Senate Bill 1913 (Chapter 695, Statutes of 2004) requires graduates of foreign pharmacy schools to become certified by the FPGEC. FPGEC has the same degree and education requirements specified in section 4200 which makes board evaluation of those standards redundant.
Status: Rulemaking Notice Published February 2, 2005.

Section 1725. - Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.
Summary: These are technical changes and conforms to the proposed language in section 1720 regarding recognized schools of pharmacy.
Status: Rulemaking Notice Published February 2, 2005.

Section 1726. Supervision of Intern Pharmacists.
Summary: Interns are no longer required to be supervised by preceptors. Accordingly, references to preceptors are eliminated.
Status: Rulemaking Notice Published February 2, 2005.

Section 1727. - Intern Pharmacist.
Summary: Senate Bill 1913 (Chapter 695, Statutes of 2004) establishes the standards for issuing intern pharmacist licenses in Section 4208 of the Business and Professions Code and are inconsistent with existing provisions of this section.
Status: Rulemaking Notice Published February 2, 2005.

Section 1728. - Requirements for Examination.
Summary: The proposed regulation will streamline the board's application process by requiring pharmacist candidates to have completed all other requirements for licensure prior to applying to take the licensure examinations. The intern hour requirements have been amended to eliminate the first year maximum and preceptor supervision requirements to reflect changes to the pharmacy curriculum in ACPE accredited pharmacy schools.
Status: Rulemaking Notice Published February 2, 2005.

Section 1732. - Definitions.
Summary: The proposed regulation would eliminate unnecessary definitions.
Status: Rulemaking Notice Published February 2, 2005.

Section 1732.05. - Accreditation Agencies for Continuing Education.
Summary: The changes update and clarify existing requirements for continuing education accreditation agencies.
Status: Rulemaking Notice Published February 2, 2005.

Section 1732.1. - Requirements for Accredited Providers.
Summary: The changes update and clarify existing requirements for continuing education providers.
Status: Rulemaking Notice Published February 2, 2005.

Section 1732.2. - Board Accredited Continuing Education.
Summary: The changes update and clarify existing requirements for Board of Pharmacy accredited continuing education providers.
Status: Rulemaking Notice Published February 2, 2005.

Section 1732.3. - Requirements for Continuing Education Courses
Summary: The changes update and clarify existing requirements for continuing education courses.
Status: Rulemaking Notice Published February 2, 2005.

Section 1732.4. - Provider Audit Requirements.
Summary: The proposed changes make minor technical changes.
Status: Rulemaking Notice Published February 2, 2005.

Section 1732.5 – Renewal Requirements for Pharmacist
The proposed changes make minor technical changes.
Status: Rulemaking Notice Published February 2, 2005.

Section 1732.6. - Exemptions.
Summary: The proposed changes make minor technical changes.
Status: Rulemaking Notice Published February 2, 2005.

Section 1732.7. - Complaint Mechanism.
Summary: The proposed changes make minor technical changes.
Status: Rulemaking Notice Published February 2, 2005.

Section 1745. - Partial Filling of Schedule II Prescriptions.
Summary: Changes made by Senate Bill 151 (Chapter 406, Statutes of 2003) allow the period for partial filling to be extended to 60 days and expands the authority to perform partial fills when a pharmacy does not have an adequate supply to fill the entire prescription in conformance with 21CFR section 1306.13. These changes will provide patients and pharmacists with greater flexibility when handling Schedule II prescriptions.
Status: Rulemaking Notice Published February 2, 2005.

Section 1749. - Fee Schedule.
Summary: The proposed regulation includes minor technical changes and the following substantive changes:

1. Subdivision (l) eliminates language relating to the extension of an intern pharmacist license in conformance with Business and Professions Code section 4208 which prohibits the extension or renewal of an intern pharmacist license.
2. Subdivision (m) is eliminated because this fee is specified in statute (Business and Professions Code section 4400) and existing language duplicates that provision.
3. Subdivision (n) is eliminated to conform with changes to continuing education regulations proposed in this rulemaking.
4. Subdivision (p) is eliminated to conform with changes regarding foreign graduates proposed in this rulemaking.
5. Subdivision (r) is eliminated because the board no longer regulates medical device retailers.

Status: Rulemaking Notice Published February 2, 2005.

Section 1750. - Fee Schedule--Health and Safety Code.
Summary: This section is repealed to conform with the repeal of its authorizing statute (section 11127 of the Health and Safety Code).

Status: Rulemaking Notice Published February 2, 2005.

Awaiting Notice

Section 1717 – Automated Dispensing Machines

Summary: The proposed regulation would regulate the use of automated dispensing machines.

Attachment 1

BOARD OF PHARMACY
2005 RULEMAKING CALENDAR

SCHEDULE A: PROPOSED REGULATIONS IMPLEMENTING STATUTES ENACTED DURING THE YEAR 2004

Subject:	CCR Title & Sections Affected:	Statutes Being Implemented:
Pharmaceutical Practices	Title 16, Amend Section 1717e Adopt Section 1712	SB 1913

Responsible Agency Unit:	Contact Person & Phone Number:	Projected Dates:			
		Notice:	Hearing:	Adoption:	To OAL:
Board of Pharmacy	Jan E. Perez, (916) 445-5014	07/2005	10/2005	10/2005	12/2005

Subject:	CCR Title & Sections Affected:	Statutes Being Implemented:
Delivery of Prescriptions	Title 16, Add Section 1713	None.

Responsible Agency Unit:	Contact Person & Phone Number:	Projected Dates:			
		Notice:	Hearing:	Adoption:	To OAL:
Board of Pharmacy	Jan E. Perez, (916) 445-5014	10/2005	01/2006	01/2006	03/2006

Subject:	CCR Title & Sections Affected:	Statutes Being Implemented:
Compounding	Title 16, Repeal Sections 1716.1, 1716.2 Add Sections 1735-1735.7	None.

Responsible Agency Unit:	Contact Person & Phone Number:	Projected Dates:			
		Notice:	Hearing:	Adoption:	To OAL:
Board of Pharmacy	Jan E. Perez, (916) 445-5014	11/2005	01/2006	01/2006	04/2005

BOARD OF PHARMACY
2005 RULEMAKING CALENDAR

SCHEDULE B: PROPOSED REGULATIONS IMPLEMENTING STATUTES ENACTED PRIOR TO THE YEAR 2004

<table>
<tr><td colspan="2">Subject:</td><td colspan="2">CCR Title & Sections Affected:</td><td colspan="4">Statutes Being Implemented:</td></tr>
<tr><td>Responsible Agency Unit:
Board of Pharmacy</td><td colspan="2">Contact Person & Phone Number:
Jan E. Perez (916) 445-5014 x 4016</td><td colspan="4">Projected Dates:</td></tr>
<tr><td></td><td></td><td>Notice:</td><td>Hearing:</td><td>Adoption:</td><td>To OAL:</td></tr>
<tr><td colspan="6">Report on the status of all uncompleted rulemaking described on previous calendars:

Self Assessment of a Pharmacy by the Pharmacist in Charge, Title 16 Section 1715- Adopted 01/20/05 – to OAL April 2005

Application for Pharmacist Examination and Licensure, Title 16 Section 1720 - Adopted 01/20/05 – to OAL April 2005

Fee Schedule, Title 16 Section 1749 - Adopted 01/20/05 – to OAL April 2005</td></tr>
<tr><td colspan="6"></td></tr>
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Board Sponsored Legislation

ASSEMBLY BILL No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend Sections 4037 and 4051 of, to add Section 4019.5 to, to repeal Section 4033 of, and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as introduced, Negrete McLeod. Pharmacy: compounding of prescription drugs.

The Pharmacy Law provides for the licensing and regulation of pharmacists and associated persons by the California State Board of Pharmacy. A violation of the law is a crime.

This bill would define compounding of a prescription drug for the purposes of that law and would make other related changes in that regard. Because this bill would revise the definition of a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4019.5 is added to the Business and Professions Code, to read:

4019.5. (a) "Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription:

(1) Altering the dosage form, flavor, or delivery system of a drug.

(2) Altering the strength of a drug.

(3) Combining components or active ingredients.

(4) Preparing a drug product from bulk chemicals.

(b) "Compounding" shall not include the reconstitution of a drug pursuant to the manufacturer's direction for oral, rectal, or topical administration.

SEC. 2. Section 4033 of the Business and Professions Code is repealed.

~~4033. (a) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.~~

~~(b) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.~~

~~(c) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.~~

SEC. 3. Section 4037 of the Business and Professions Code is amended to read:

4037. (a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where ~~prescriptions are compounded~~ *dangerous drugs and dangerous devices are stored.* "Pharmacy" includes, but is not limited to, any area, place, or premises ~~described in a~~

~~license issued~~ *licensed* by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, ~~manufactured,~~ derived, compounded, ~~or~~ repackaged, ~~and from which the controlled substances, dangerous drugs, or dangerous devices are~~ furnished, sold, or dispensed at retail.

(b) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

SEC. 4. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to ~~manufacture,~~ compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

SEC. 5. Section 4123 of the Business and Professions Code is repealed.

~~4123. Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.~~

SEC. 6. Section 4123 is added to the Business and Professions Code, to read:

4123. (a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.

(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for that drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

(d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients.

(e) A pharmacy may only base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

(f) Notwithstanding any other provision of this chapter, a pharmacist may do both of the following:

(1) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, provided that the drug is not compounded prior to the receipt of the prescription.

(2) Repackage a drug previously dispensed to the patient at the request of the patient or the patient's agent.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a

crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Bills of Interest

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 21 **VERSION: INTRODUCED**

AUTHOR: LEVINE **SPONSOR: LEVINE**

RECOMMENDED POSITION:

SUBJECT: PHARMACIST: CONTRACEPTIVE DEVICES

Existing Law:

1) Permits pharmacists to dispense emergency contraception (EC) without a prescription if a protocol is established with a prescriber or the protocol established by the board. (B&P 4052)

2) Establishes procedures for dispensing EC without a prescription. (CCR 1746)

3) Requires a pharmacist who declines to distribute EC to refer the patient to another EC provider. (CCR 1746)

This Bill:

Prohibits a pharmacist from declining to dispense a contraceptive or EC pursuant to a prescription. (B&P 4069 Added)

Comment:

1) Author's Intent. The author's intent is to insure that pharmacists do not refuse to dispense EC to patients. Author's staff acknowledges that the bill does not contain an opt-out clause for pharmacists and that the bill is likely to be amended prior to its first committee hearing.

2) Consistency. AB 21 is inconsistent with current EC regulations that allow a pharmacist to opt-out of filling a prescription, based on moral, ethical or religious grounds. Board regulations direct that such patients be referred to another pharmacist to fill a prescription.

3) Enforcement. Enforcement of AB 21 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacist's refusal to dispense EC. Consequently, if AB 21 were enacted, the board does not anticipate a huge increase in consumer complaints regarding refusal to fill prescriptions.

4) Necessity for Law? Pharmacy law and regulation (B&P 4052 & CCR 1746) require a pharmacist to fill EC prescriptions, or refer a patient to another pharmacist or pharmacy when a pharmacist is unable to fill a prescription for EC. The board has not encountered any problems with enforcing this law. Consequently, it would seem as though AB 21 duplicative of current law.

5) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation. SB 545 (Chapter 652, Statutes of 2003) clarified many of the provisions in SB 1169. The board took a neutral position on the bill.

6) Related Legislation. AB 644 (Ortiz 2005) Dispensing of Prescriptions, would require a pharmacist to dispense a lawful prescription unless one of the following circumstances exists: 1) dispensing the prescription is contrary to law or is contraindicated for the patient; 2) the pharmacy does not have the dangerous drug that was prescribed in its stock; 3) the pharmacist refuses on ethical, moral, or religious grounds to dispense a dangerous drug pursuant to an order or prescription providing the pharmacist has notified their employer, in writing, and the pharmacy has established protocols that ensure that the patient has timely access to the prescribed dangerous drug despite the pharmacist's refusal to dispense the prescription.

7) History.

2005
Feb. 15 Referred to Coms. on HEALTH and B. & P.

2004
Dec. 7 From printer. May be heard in committee January 6.
Dec. 6 Read first time. To print.

ASSEMBLY BILL No. 21

Introduced by Assembly Member Levine

December 6, 2004

An act to add Section 4069 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 21, as introduced, Levine. Pharmacists: contraceptive devices.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Under existing law, a violation of those provisions is a crime.

This bill would prohibit a pharmacist from declining to dispense a contraceptive or emergency contraceptive.

Because the bill would specify an additional requirement under the Pharmacy Law, a violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4069 is added to the Business and Professions Code, to read:

4069. Notwithstanding any other provision of law, a pharmacist shall not decline to dispense a contraceptive or an emergency contraceptive pursuant to a prescription.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 71 **VERSION: AMENDED FEB 11, 2005**

AUTHOR: CHAN **SPONSOR: CHAN**

RECOMMENDED POSITION:

SUBJECT: PHARMACEUTICALS: ADVERSE DRUG REACTIONS: OFFICE OF CALIFORNIA DRUG SAFETY WATCH.

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers about adverse drug reactions.

This Bill:

1) Establishes the Office of California Drug Safety Watch (office) within the Department of Health Services (DHS).

2) Requires the office to establish a toll-free telephone number for the purpose of receiving reports of adverse drug reactions.

3) Requires the office to establish a Web site to provide up-to-date information to the public about adverse drug reactions.

4) Requires the office to maintain a database of adverse drug reaction reports.

5) Requires the Office to act as a liaison with all appropriate parties, including the FDA, drug manufacturers, pharmacists, physicians, health care providers, and consumer drug safety organizations, to ensure the speedy and accurate flow of information about important drug safety issues.

(H&S 111657 Added)

Comment:

1) Author's Intent. The author is concerned about drug safety and the perceived inability of the Federal government to take action to warn the public about potentially dangerous drugs. The author's staff acknowledges that the bill, as currently written, may not be the exact solution to the problem, rather they see the measure as a starting point for discussion and are open to amendments.

2) Concerns. The bill would essentially duplicate the FDA's MedWatch program. This could result in confusion among health care professionals as to which program they should report

adverse drug reactions to. As a result, reports of drug problems could be under reported. Additionally, the bill does not appropriate money to DHS fund the new program.

3) FDA, Center for Drug Evaluation and Research (CDER). CDER evaluates the safety profiles of drugs available to American consumers using a variety of tools and disciplines throughout the life cycle of the drugs. CDER maintains a system of postmarketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug development process. CDER learns about adverse events through required reporting by companies and through voluntary reports submitted to FDA's MedWatch program, which together total more than 250,000 reports per year. Staff in the Office of Drug Safety use this information to identify drug safety concerns and recommend actions to improve product safety and protect the public health. Activities include updating drug labeling, providing more information to the community, implementing or revising a risk management program, and, on rare occasions, reevaluating approval or marketing decisions. CDER also works with drug companies to reduce medication errors related to confusing labels, labeling, drug packaging, and drug names that look alike or sound alike.

Recent government reports and the national media have been critical of the FDA's ability to do its job. Most accounts report that the system could be improved, but it is not broken. The FDA, reacting to political pressure, is in the process of reviewing its programs and looking for ways it can increase drug safety.

4) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

AB 72 (Frommer) Prescription Drugs: Manufacturer Reporting Requirement, would require a manufacturer of prescription drugs that offers for sale, transfers, or furnishes a prescription drug in the state to submit a report of health studies to DHS that have been or are being conducted for each prescription drug it sells, transfers, or furnishes in the state. The measure would also give the Attorney General the authority to bring a civil action to enforce the requirements of bill.

AB 380 (Alquist) Drugs: Adverse event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program. (MedWatch is a voluntary reporting program that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.)

5) History.

2005	
Feb. 15	Re-referred to Com. on HEALTH.
Feb. 11	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Com. on HEALTH.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AMENDED IN ASSEMBLY FEBRUARY 11, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 71

Introduced by Assembly Members ~~Frommer and~~ Chan *and Frommer*
(Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, and Pavley)

January 3, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, ~~Frommer~~ Chan. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department ~~to perform duties related to adverse drug reactions. These duties would include, among others, establishing~~ *and would require the office to establish* a toll-free telephone number for the purpose of receiving reports of adverse drug reactions, ~~establishing~~ *establish* a Web site to provide up-to-date information to the public about adverse drug reactions, ~~and maintaining~~ *maintain* a database of adverse drug reaction reports, *and act as a liaison with all appropriate parties to ensure the speedy and accurate flow of information about important drug safety issues*.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Since 1997, when the United States Food and Drug Administration (FDA) allowed drug manufacturers to advertise directly to consumers, the amount spent on advertising has risen dramatically.

(b) According to the United States General Accounting Office (GAO) report, the pharmaceutical industry spent $2.7 billion in 2001 on direct-to-consumer advertising. A December 6, 2004, New York Times report states that such spending has reached $3.8 billion.

(c) According to the same GAO report, while overall spending on drug promotion was less than spending on research and development ($19.1 billion versus $30.3 billion), spending on direct-to-consumer advertising is increasing at a faster rate than overall drug promotion spending or spending on research and development. Between 1997 and 2001, the increase in direct-to-consumer advertising was 145 percent compared to a 59 percent increase for research and development.

(d) Although the FDA is responsible for postmarket surveillance of prescription drugs, numerous concerns have been raised about the adequacy of these efforts.

(e) An unpublished internal FDA study from 2002 revealed that 18 percent of FDA scientists reported being pressured to approve a new drug "despite reservations about the safety, efficacy or quality of the drug."

(f) A 1999 FDA survey and a Kaiser Family Foundation survey both found that more than 50 million people respond to drug advertisements by asking their doctor whether the advertised medications might work for them. At the same time, both surveys showed that almost 60 percent of consumers found the side-effect warnings in these advertisements to be inadequate.

(g) Pressure to get new drugs to market, combined with the vast amount of drug marketing undertaken by manufacturers, make it difficult to address a threat once it is identified. Recent

studies linking the use of popular, widely promoted prescription drugs to serious public health concerns point to the need for greater oversight to protect the public.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall ~~perform~~ *do* all of the following ~~duties~~:

(a) Establish a toll-free telephone number for the purpose of receiving reports of adverse drug reactions.

(b) Establish a Web site to provide up-to-date information to the public about adverse drug reactions.

(c) Maintain a database of adverse drug reaction reports.

(d) Act as a liaison with all appropriate parties, including the United States Food and Drug Administration, drug manufacturers, pharmacists, physicians, health care providers, and consumer drug safety organizations, to ensure the speedy and accurate flow of information about important drug safety issues.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 72 **VERSION: INTRODUCED**

AUTHOR: FROMMER **SPONSOR: FROMMER**

RECOMMENDED POSITION:

SUBJECT: PRESCRIPTION DRUGS: MANUFACTURER REPORTING REQUIREMENT

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establishes the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers to report adverse drug reactions.

This Bill:

1) Requires a manufacturer of prescription drugs that offers for sale, transfers, or furnishes a prescription drug to any person or entity in this state, to submit a report to the Department of Health Services (DHS) of health studies that have been or are being conducted for each prescription drug it sells, transfers, or furnishes in this state. (H&S 130700 Added)

The report would: 1) include all studies pertaining to each prescription drug, whether the results are positive, negative, neutral, or inconclusive; and 2) be consistent with requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) that apply to the dissemination of information by a drug manufacturer to a state governmental agency. (H&S 130700 Added)

2) Gives the Attorney General the authority to bring a civil action to enforce the requirements of measure and to asses and recover civil penalties of up to $25,000 for each first violation, $50,000-$100,000 for each second violation, and $150,000-$200,000 for each subsequent violation. Recovered penalties would be deposited in the State Treasury. (H&S 130700 Added)

Comment:

1) Author's Intent. The author is concerned that the Federal government is not doing enough to protect consumers by monitoring the post-marketing safety of approved drug and therapeutic biologic products.

2) Reporting Requirements. While the measure requires drug manufactures to submit a report to the DHS of health studies that have, or are being conducted on each prescription drug it sells in this state, the measure does not require DHS to do anything with the information once it is received. Nor does the bill appropriate funds to DHS to process the information. Is it the intent of the legislation for DHS to review the information? Enter it into a database? Analyze the studies listed in reports? Make findings? Notify the public of dangerous drugs? Or lobby the FDA to take action against harmful drugs?

3) FDA, Center for Drug Evaluation and Research (CDER). CDER evaluates the safety profiles of drugs available to American consumers using a variety of tools and disciplines throughout the life cycle of the drugs. CDER maintains a system of postmarketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug development process. CDER learns about adverse events through required reporting by companies and through voluntary reports submitted to FDA's MedWatch program, which together total more than 250,000 reports per year. Staff in the Office of Drug Safety use this information to identify drug safety concerns and recommend actions to improve product safety and protect the public health. Activities include updating drug labeling, providing more information to the community, implementing or revising a risk management program, and, on rare occasions, reevaluating approval or marketing decisions. CDER also works with drug companies to reduce medication errors related to confusing labels, labeling, drug packaging, and drug names that look alike or sound alike.

Recent government reports and the national media have been critical of the FDA's ability to do its job. Most accounts report that the system could be improved, but it is not broken. The FDA, reacting to political pressure, is in the process of reviewing its programs and looking for ways it can increase drug safety.

4) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session. AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a toll-free telephone number for the purpose of receiving reports of adverse drug reactions; 2) establish a Web site to provide up-to-date information to the public about adverse drug reactions; 3) maintain a database of adverse drug reaction reports; and 4) act as a liaison with appropriate parties to ensure the speedy and accurate flow of information about important drug safety issues.

AB 380 (Alquist) Drugs: Adverse event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program.

5) History.

2005	
Jan. 18	Referred to Coms. on HEALTH and JUD.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

ASSEMBLY BILL No. 72

Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, Pavley, and Salinas)

January 3, 2005

An act to add Division 114 (commencing with Section 130700) to the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 72, as introduced, Frommer. Prescription drugs: manufacturer reporting requirement.

Existing law regulates the labeling, sale, and use of prescription drugs and devices.

This bill would require a prescription drug manufacturer that offers for sale, transfers, or otherwise furnishes prescription drugs to any person or entity in this state to submit a report to the State Department of Health Services of health studies that have been or are being conducted by or on behalf of that manufacturer pertaining to those drugs. The bill would require the report to be consistent with federal laws applicable to information disseminated by drug manufacturers to a state governmental agency.

This bill would authorize the Attorney General to bring civil actions to enforce the reporting requirements and recover civil penalties that may be assessed by the Attorney General under the bill.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 114 (commencing with Section 130700) is added to the Health and Safety Code, to read:

DIVISION 114. PRESCRIPTION DRUGS

CHAPTER 1. DRUG MANUFACTURER HEALTH STUDIES REPORTING

130700. (a) Any manufacturer of prescription drugs that offers for sale, transfers, or otherwise furnishes a prescription drug to any person or entity in this state shall submit a report to the State Department of Health Services of health studies that have been or are being conducted by or on behalf of that manufacturer regarding each prescription drug it sells, transfers, or otherwise furnishes to a person or entity in this state.

(b) Subject to subdivision (c), the report shall include all studies pertaining to each prescription drug, whether the results are positive, negative, neutral, or inconclusive.

(c) The report shall be consistent with requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) that apply to the dissemination of information by a drug manufacturer to a state governmental agency.

130705. (a) The Attorney General may bring a civil action to enforce the requirements of Section 130700.

(b) (1) The Attorney General may assess and recover a civil penalty, as specified in paragraph (2), against a drug manufacturer for each finding of a violation of Section 130700 in a civil action brought under this section.

(2) A drug manufacturer that violates Section 130700 is liable for civil penalties of up to twenty–five thousand dollars ($25,000) for each first violation, not less than fifty thousand dollars ($50,000) nor more than one hundred thousand dollars ($100,000) for each second violation, and not less than one hundred fifty thousand dollars ($150,000) nor more than two hundred thousand dollars ($200,000) for each subsequent violation.

(3) Any civil penalty recovered by the Attorney General under this subdivision shall be deposited in the State Treasury.

(c) In any action under this section in which judgment is entered against the defendant, the Attorney General shall be awarded reasonable attorney's fees together with the costs of suit.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 73 **VERSION: AS AMENDED MARCH 17, 2005**

AUTHOR: FROMMER ET AL. **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: DRUG IMPORTATION

Existing Law:

1) Requires non-resident pharmacies to be licensed by the board. (B&P 4112)

2) Prohibits the importation of prescription drugs except by a drug manufacturer. (21CFR 381)

This Bill:

1) Makes a number of legislative findings about the costs and necessity of prescription drugs.

2) Requires the Department of Health Services (DHS) to establish a Web site on or before July 1, 2006 that will provide consumers with information on how to purchase prescription drugs more affordably. The Web site shall include the following information:

a. The availability of a prescription drug benefit through Medicare, including the Voluntary Prescription Drug Benefit.
b. Discount drug programs available through the state.
c. Discount drug programs operated by drug manufacturers.
d. Canadian pharmacies that are approved by the department.
e. International pharmacies (Canada, England, and Ireland) that provide mail order service to the Untied States and contract with the department.
f. Links to any other Web sites deemed appropriate by the department.

(H&S 110242 Added)

3) Requires the Web site to include price comparisons between typical pharmacy prices and international pharmacy prices for the 50 most commonly prescribed drugs.

(H&S 110242 Added)

4) Establishes the requirements that must be met for the department to "certify" a pharmacy located in Canada, England, or Ireland to include:

a. Verification of licensure by the appropriate province or country.
b. Compliance with the requirements that must be met by non-resident pharmacies. This determination will be made in consultation with the board.
c. Requires a prescription from the patient's personal physician.
e. Requires a patient medical history.
f. Requires a signed patient agreement.

g. Requires prescriptions to be mailed in original packaging.

h. Requires physical address and phone number for the pharmacy on the pharmacy Web site.

i. Prohibits the pharmacy from furnishing the following drugs:

i. Controlled substances.

ii. Biologics.

iii. Infused drugs.

iv. Intravenous drugs.

v. Drugs inhaled during surgery.

vi. Drugs requiring refrigeration or that are otherwise inappropriate for mail delivery.

j. Sale of only drugs approved by the country in which the pharmacy is located.

k. Comply with California law relating to drug pedigree.

l. Prohibits requiring patients to sign a waiver of liability.

m. Requires the pharmacy to maintain a customer service department.

n. Requires the pharmacy to employ professionals that are licensed in good standing.

o. Requires the pharmacy to comply with California privacy laws.

p. Prohibits filling a prescription if the patient hasn't taken the drug previously.

q. Prohibits furnishing drugs that have no equivalent approved by the FDA.

(H&S 110242 Added)

5) Permits the department to remove approved pharmacies from the Web site if the pharmacy fails to meet any of the above listed requirements. (H&S 110242 Added)

6) Permits the department to assess a fee on international pharmacies to fund this act. (H&S 110242 Added)

Comment:

1) Author's Intent. The authors' intent is to provide relief for Californians who are "fed up with sky-high pharmaceutical drug prices and concerned about the safety of those drugs." AB 73 is part of an eight-bill package being offered by Assembly Democrats to bring down the cost of prescription drugs sold in California.

2) Importation. Existing federal law generally restricts the importation of prescription drugs to drug manufacturers. Federal law can permit the importation of prescription drugs by drug wholesalers and pharmacies if the Secretary of Health and Human Services (Secretary) issues a finding that such a practice would be safe. Such a finding has not been issued by the Secretary.

The Food and Drug Administration (FDA) has for many years allowed individuals to purchase drugs abroad in limited amounts and bring them into the United States for personal use. Recent statements by FDA officials have reinforced that the FDA does not intend to prosecute individuals who import drugs for their own use. However, the FDA has taken legal action against some storefronts that assist consumers in ordering drugs from Canadian pharmacies at lower prices. The FDA has also taken legal action against entities that serve as middlemen between Canadian drug suppliers and those state and local governments that have sought to purchase Canadian drugs for their beneficiaries.

However, Congress has recently introduced legislation (HR 328) that would change the rules and allow importation of drugs from Canada and select countries in the European Community (EC).

3) Price Controls. Consumers seek to purchase drugs from Canadian and EC pharmacies to save money. Drug prices are lower in Canada because the Canadian government has a system to control drug prices. ***Branded*** drugs can commonly be purchased from Canadian pharmacies at substantial discounts. However, US prices are generally lower for ***generic*** drugs.

4) Affordability. The board has been sympathetic to the difficulty of those without drug insurance have to obtain the drugs they need.

Much of the public debate regarding the importation of drugs from Canada has focused on the safety of imported drugs. Consumers are seeking Canadian and EC drugs because of lower prices not because of problems with drug availability or because of the convenience of the Canadian pharmacies.

5) Other States. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

6) State Legislation. AB 1957 (Frommer et.al. 2004), Drug Importation, was introduced last session, AB 73 is similar to AB 1957 except AB 73 expands the list of countries for drug importation to include England and Ireland, or any other country. The board opposed AB 1957 and the Governor vetoed the measure. In the Governor's veto message he states "...importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability.... In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians."

Related Bills this Session

AB 74 (Gordon and Frommer) California Rx Prescription Drug Hotline. This measure would require DHS to establish a drug hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

AB 75 (Frommer) Pharmaceutical Assistance Program. This bill would establish the California Rx Plus State Pharmacy Assistance Program, to be administered by DHS. The bill would authorize DHS to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts for lower income Californians.

AB 76 (Frommer) Office of Pharmaceutical Purchasing. This measure would instead establish within the California Health and Human Services Agency, the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies. The bill would authorize the office to conduct specified activates in order to negotiate the lowest prices possible for prescription drugs.

SB 19 (Ortiz) California Rx Program. This bill is sponsored by the Governor and would establish a state program to negotiate for lower price prescription drugs for lower income Californians.

7) History.

2005	
Mar. 17	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.

Jan. 4 From printer. May be heard in committee February 3.
Jan. 3 Read first time. To print.

8) Support and Opposition. None on File

List of Support and Opposition for AB 1957 (Frommer 2004)

Support: AARP California
AIDS Healthcare Foundation
AIDS Project Los Angeles
Alzheimer's Association California Council
American Federation of State, County and Municipal Employees
Area Agency on Aging Advisory Council for San Luis Obispo and Santa Barbara Counties
Being Alive Los Angeles, Inc.
California Alliance for Retired Americans
California Commission On Aging
California Faculty Association
California Federation of Teachers
California Independent Pubic Employees Legislative Council
California Labor Federation
California Medical Association
California Nurses Association
California Public Interest Research Group
California School Employees Association
California Seniors Coalition
California Small Business Association
California State Employees Association
California Teachers Association
Congress of California Seniors
Consumer Federation of California
Consumers Union
Gray Panthers
Health Access California
Lieutenant Governor, Cruz Bustamante
National Association of Social Workers, California Chapter
Northern Sierra Rural Health Network
Office of the Attorney General
Older Women's League of California
Peace Officers Research Association of California
Santa Clara County Board of Supervisors
Service Employees International Union
The Foundation for Taxpayer and Consumer Rights
United Nurses Association of California/Union of Health Care Professionals
Western Center on Law and Poverty

Oppose: Abbott Laboratories
Amyotrophic Lateral Sclerosis
Aventis Pharmaceuticals, Inc.
Bristol-Myers Squibb Company
California Chamber of Commerce
California Healthcare Institute
National Association of Cancer Patients, California Chapter
Novartis Pharmaceuticals Corporation
Pharmaceutical Research and Manufacturers of America
San Joaquin County Commission on Aging
Pfizer Inc.
Seniors Coalition

Silicon Valley Manufacturing Group
One individual

AMENDED IN ASSEMBLY MARCH 17, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 73

Introduced by Assembly Members Frommer and Chan
(Coauthors: Assembly Members *Baca,* Bass, *Berg, Coto, De La Torre,* Evans, *Goldberg,* Gordon, *Hancock, Klehs,* Koretz, *Leno, Levine,* Nava, Pavley~~, and Salinas~~, *Ridley-Thomas, Ruskin, Salinas, and Torrico*)

January 3, 2005

An act to ~~add Section 14982 to the Government Code, and to~~ add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 73, as amended, Frommer. Prescription drugs: importation: procurement.

~~(1)~~ Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

Existing law, the Pharmacy Law, provides that any pharmacy located outside of this state that delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy and requires a nonresident pharmacy to register with the California State Board of Pharmacy and comply with all lawful directions of, and requests for information from, the state in which it is a resident.

Existing federal law requires any establishment within any foreign country engaged in the manufacture, preparation, propagation,

compounding, or processing of a drug that is imported or offered for import into the United States to register with the federal Secretary of Health and Human Services, report a list of each drug introduced for commercial distribution, and provide required information and statements.

This bill would establish the California Rx Prescription Drug Web Site Program. The bill would require the State Department of Health Services to administer the program and establish a Web site on or before July 1, 2006, to provide information to California residents about options for obtaining prescription drugs at affordable prices. The bill would require that the Web site, at a minimum, provide information about, and establish electronic links to, certain federal, state, and pharmaceutical programs, pharmacies that are located in Canada, ~~England~~ *the United Kingdom*, and Ireland and that meet specified requirements, and other Web sites.

This bill would authorize the department to assess a fee on international pharmacies that the department reviews for possible inclusion on the Web site to offset the cost of reviewing those pharmacies. The bill would require the department's Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site.

~~(2) Existing law authorizes the Department of General Services to administer a coordinated prescription drug bulk purchasing program under which the department may enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs and obtain from them discounts, rebates, and refunds as permissible under federal law. Existing law requires certain state agencies to participate in the program and authorizes any other state, local, and public agency governmental entity to elect to participate in the program.~~

~~This bill would require the department to coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements to be listed on the California Rx Prescription Drug Web site. The bill would require the department, on or before January 1, 2007, to conduct the review and report to the Legislature. The bill would require the report to~~

~~recommend options to facilitate more cost-effective acquisition of prescription drugs. The bill would authorize the department to establish pilot programs under which purchases of prescription drugs from international pharmacies would be made at reduced prices for purposes of state departments and agencies.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) The United States is the largest trade market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand name pharmaceuticals in the world.

(c) Increased spending on prescription drugs is a significant driver of increases in overall health care costs, with spending nationwide on prescription drugs rising over 15 percent each year from 2000 to 2002.

(d) Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers, as evidenced by federal government statistics *that* show that in 2002 the increase in consumers' out-of-pocket costs for prescription drugs was greater than the increase in out-of-pocket costs for all other health care expenditures.

(e) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that year.

(f) The rising cost of prescription drugs also places a significant burden on state government, with the cost of providing prescription drugs to Medi-Cal beneficiaries, to inmates of the Department of Corrections, and to other participants in state programs growing in some cases at over 20 percent annually in recent years.

(g) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford

the medication they need to stay healthy, as shown by a study by the RAND Corporation that found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20 percent and subsequently experienced higher rates of emergency room visits and hospital stays.

(h) The rising cost of prescription drugs places a disproportionate burden on communities of color, as shown in a report from the Center for Studying Health System Change that found that African-Americans are about 75 percent and Latinos about 50 percent more likely than nonminorities to not have purchased a prescription drug in 2001 because of cost issues.

(i) A prescription drug is neither safe nor effective to an individual who cannot afford it.

(j) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

~~SEC. 2. Section 14982 is added to the Government Code, to read:~~

~~14982. (a) The Department of General Services shall coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements of Section 110242 of the Health and Safety Code. State departments to be reviewed shall include, but not be limited to, all of the following:~~

~~(1) The State Department of Health Services.~~

~~(2) The Managed Risk Medical Insurance Board.~~

~~(3) The Department of General Services.~~

~~(4) The Department of Corrections.~~

~~(5) The California Public Employees' Retirement System (CalPERS).~~

~~(b) The Department of General Services shall, on or before January 1, 2007, conduct the review required under subdivision (a) and report its findings based on that review to the Legislature. The report shall recommend options to the Legislature, including conducting pilot programs, to facilitate more cost-effective acquisition of prescription drugs. The recommendations shall~~

~~include a determination of the need to seek any federal approvals or waivers.~~

~~(c) The Department of General Services may establish pilot programs under which purchases of prescription drugs from international pharmacies are made at reduced prices for purposes of state departments and agencies.~~

~~(d) As a condition of implementing any pilot program under this section, the Department of General Services shall seek and obtain all appropriate federal waivers and approvals necessary for the implementation of that pilot program.~~

~~SEC. 3.~~

SEC. 2. Article 5 (commencing with Section 110242) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Prescription Drug Web Site Program

110242. (a) The California Rx Prescription Drug Web Site Program is hereby established.

(b) The State Department of Health Services shall administer the program. The purpose of the program shall be to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

(c) The department shall establish a Web site on or before July 1, 2006, which shall, at a minimum, provide information about, and electronic links to, all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

(4) International pharmacies that provide mail-order service to the United States and who meet the requirements of paragraph (2) of subdivision (d).

(5) Other Web sites as deemed appropriate by the department that help California residents to safely obtain prescription drugs

at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

(d) (1) The Web site shall include price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in the state and by international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site pursuant to paragraph (2).

(2) The Web site shall provide information about, and establish electronic links to, pharmacies that are located in Canada, ~~England~~ *the United Kingdom*, and Ireland that provide mail-order services to the United States and that meet all of the following requirements:

(A) Are licensed by the province or country, as appropriate, in which they are located.

(B) Comply with the requirements of a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code, except that for purposes of this section all references to "state" in subdivision (d) of Section 4112 of the Business and Professions Code shall be deemed to refer to the province or other licensing jurisdiction in which the pharmacy is located. Compliance with this subparagraph shall be determined by the department in consultation with the California State Board of Pharmacy.

(C) Require a prescription from a patient's personal physician, who is licensed to practice in the United States.

(D) Require the completion of a relevant medical history profile.

(E) Require a signed patient agreement.

(F) Ship prescription drugs in tamperproof original manufacturer containers to individuals in the United States, unless the consumer requests to receive the drug in a childproof container.

(G) Include a physical address and pharmacy license number on its company Web site.

(H) Do not furnish any of the following:

(i) A controlled substance.

(ii) A biological product, as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

(iii) An infused drug, including, a peritoneal dialysis solution.

(iv) An intravenously injected drug.

(v) A drug that is inhaled during surgery.

(vi) A drug that requires refrigeration or cannot be safely shipped by mail.

(vii) More than the prescribed amount of a drug or more than a three-month supply of any drug.

(viii) A drug that the consumer indicates he or she has not previously taken.

(ix) A drug for which there is no equivalent drug approved for sale in the United States by the federal Food and Drug Administration.

(I) Sell only prescription drugs that have been approved for sale in the country in which the pharmacy is located by the agency responsible for ensuring the safety of prescription drugs in that country.

(J) Comply with state law regarding the documentation of the pedigree of prescription drugs.

(K) Does not require a consumer to sign a waiver of liability or a release of liability for a negligent act by the pharmacy.

(L) Maintain a service department to respond to consumer inquiries and provide information to consumers about how they may file complaints with the provincial or other applicable licensing authority.

(M) Ensure that all physicians, pharmacists, and technicians in its employ are properly licensed and their licenses are in good standing.

(N) Comply with all personal health and medical information privacy laws applicable to pharmacies located in California.

(O) Any other requirement established by the department to ensure the safety, accessibility, and affordability of prescription drugs.

(3) A pharmacy that seeks to be linked to the department's Web site pursuant to paragraph (2) shall apply to the department. The department may enter into a contract with a pharmacy that it determines meets the requirements of paragraph (2). A contract may be renewed annually upon payment of the fee specified in paragraph (5) provided that the pharmacy continues to comply with the requirements of paragraph (2).

(4) The department may terminate a contract with, and delete an electronic link to, or information about, a pharmacy that the

department determines no longer complies with the requirements of paragraph (2). The department shall review within 30 business days any information that it receives regarding a pharmacy's compliance with the requirements of paragraph (2) and shall determine whether the information constitutes grounds for removal of the pharmacy from the Web site.

(5) The department may assess a fee on international pharmacies that the department reviews pursuant to paragraph (2) to offset the cost of reviewing those pharmacies.

(e) The department shall ensure that the Web site established pursuant to this section is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs.

(f) Any information, including the identity of an international pharmacy, to be posted on the Web site shall first be approved by professional staff of the department before it is posted.

(g) The department shall include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. The notice shall also inform consumers that a pharmacy linked to the Web site is licensed in the country in which it is located and that the department has the right to remove a pharmacy from the Web site if it violates the requirements of paragraph (2) of subdivision (d) or the terms of any agreement between the department and the pharmacy. In addition, the notice shall include a statement that the state accepts no legal liability with respect to any product offered or pharmaceutical services provided by a pharmacy linked to the Web site.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 74 **VERSION: INTRODUCED**

AUTHOR: GORDON **SPONSOR: GORDON**

RECOMMENDED POSITION:

SUBJECT: CALIFORNIA RX PRESCRIPTION DRUG HOTLINE

Existing Law:

The Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the California Department of Health Services (DHS). (H&S 109875)

This Bill:

1) Requires the DHS to establish the California Rx Prescription Drug Hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

2) Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006 and to limit the cost per call to the hotline to no more than 50 cents per call. The hotline would provide the following information:

a. Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.

b. State programs that provide drugs at discounted prices for California residents.

c. Federal programs that provide drugs at discounted prices for United States residents.

d. Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

e. Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.

f. Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies.

g. Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by 1) licensed pharmacies in the state, 2) licensed pharmacies in other states, and 3) pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

(H&S 1010243 Added)

Comment:

1) Author's Intent. The author's intent is to provide a one-stop-shop for information on how to obtain low priced prescription drugs. While much of this information is available on the Internet, the author is concerned that it's not getting to senior citizens, many of which who have never used a computer, let alone Internet.

As introduced, the measure would require DHS to establish a 1-900 telephone number for the program. The author is considering amending the bill to link the new program to an existing program and established 1-800 number. One option would be to link the program to the Health Insurance Counseling and Advocacy Program (HICAP), within California Department of Aging. HICAP assists individuals and families with Medicare problems and provides information on Medicare, Medicare supplement insurance, managed care, long-term care planning and health insurance.

2) Drug Pricing. This bill requires DHS to provide price comparisons of commonly prescribed brand name prescription drugs, including typical prices charged by instate pharmacies, pharmacies in other states, and pharmacies in Canada. The problem with this requirement is it is impossible to come up with a "typical price charged" for a given drug. The true cost of a drug is influenced by factors including, but not limited to: discounts, rebates, and reimbursement formulas available to a particular purchaser, the number of manufacturers producing a given drug, and the supply and demand for a given drug in a given geographical area. In an effort to establish a benchmark for prescription drugs, standardized terms have been developed, however each term is limited in its ability to accurately establish the true price of prescription drugs. These terms include: average manufacturer price, average sales price, average wholesale price, federal supply schedule, and wholesale acquisition cost.

3) History.

2005

Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

ASSEMBLY BILL No. 74

Introduced by Assembly Members Gordon and Frommer

January 3, 2005

An act to add Article 5 (commencing with Section 110243) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 74, as introduced, Gordon. California Rx Prescription Drug Hotline.

Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

This bill would require the department to establish the California Rx Prescription Drug Hotline, on or before July 1, 2006, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. The bill would establish a maximum cost per call to the hotline and require the hotline to provide specific information.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) Increased spending on prescription drugs is a significant driver of increases in overall health care costs.

(c) Rising out–of–pocket costs for prescription drugs are placing a growing burden on California consumers, as federal government statistics show that in 2002 the increase in consumers' out–of–pocket costs for prescription drugs was greater than the increase in out–of–pocket costs for all other health care expenditures

(d) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that period.

(e) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy.

(f) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

SEC. 2. Article 5 (commencing with Section 110243) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Precription Drug Hotline

110243. (a)The State Department of Health Services shall establish the California Rx Prescription Drug Hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

(b) The department shall establish a low–cost 1–900 telephone number on or before July 1, 2006. Callers shall be provided information about options for obtaining prescription drugs at affordable prices. The cost per call to the hotline shall not exceed 50 cents ($0.50) and the hotline shall, at a minimum, provide information about all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Federal programs that provide drugs at discounted prices for United States residents.

(4) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

(5) Other informational resources as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including, but not limited to, both of the following:

(A) Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.

(B) Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies.

(6) Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by all of the following:

(A) Licensed pharmacies in the state.

(B) Licensed pharmacies in other states.

(C) Pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

(c) The department shall ensure that the hotline established pursuant to this section is coordinated with and does not duplicate other state funded programs and services that provide information about prescription drug options and costs.

(d) Any information provided via the hotline shall first be approved by professional staff of the department.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 75 **VERSION: INTRODUCED**

AUTHOR: FROMMER **SPONSOR: FROMMER**

RECOMMENDED POSITION:

SUBJECT: PHARMACEUTICAL ASSISTANCE PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California Rx Plus State Pharmacy Assistance Program (Program) within DHS. (H&S 130501 Added)

2. Defines the terms: Program, Department (DHS), fund (California Rx Plus Program Fund), program, and qualified resident. (H&S 130500 Added)

3. Establishes the criteria for a qualified resident as:

   a. A resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines. (2005 - $38,280 for an individual and $77,400 for a family of four)

   b. A family that incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal fifteen percent or more of family income. (H&S 130500 Added)

4. Allows an individual enrolled in Medicare to participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare. (H&S 130505 Added)

5. Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in program. Requires DHS to coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program. (H&S 130515 Added)

6. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. (H&S 130518 Added)

7. Requires that no less than 95 percent of the drug rebates negotiated will be used to reduce the cost of drugs purchased by participants in the program. (H&S 130518 Added)

8. Establishes the California Rx Plus Program Fund and appropriates $5 million from the General Fund to implement the program. (H&S 130523 Added)

Comment:

1) Author's Intent. The author is concerned about the high cost of prescription drugs and the inability of uninsured individuals to pay for their medications.

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation. AB 74 (Gordon and Frommer) California Rx Prescription Drug Hotline. This measure would require DHS to establish a drug hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

AB 73 (Frommer, Chan) Safe and Affordable Drug Importation from International Pharmacies, would require DHS to set up a web site that would provide information on importing drugs from international pharmacies.

AB 76 (Frommer) Office of Pharmaceutical Purchasing. This measure would instead establish within the California Health and Human Services Agency, the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies. The bill would authorize the office to conduct specified activates in order to negotiate the lowest prices possible for prescription drugs.

SB 19 (Ortiz) California Rx Program. This bill is sponsored by the Governor and would establish a state program to negotiate for lower price prescription drugs for lower income Californians.

5) History.

2005	
Jan. 27	To Com. on RLS.
Jan. 18	From print. May be acted upon on or after February 17.
Jan. 14	Introduced. Read first time. To Com. on RLS. for assignment. To print.

ASSEMBLY BILL No. 75

Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, Pavley, and Salinas)

January 3, 2005

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to prescription drugs, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 75, as introduced, Frommer. Pharmaceutical assistance program.

Under existing law, the State Department of Health Services administers the Medi–Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Plus State Pharmacy Assistance Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program.

The bill would establish the California Rx Plus Program Fund, as a continuously appropriated fund, into which all payments received

under the program would be deposited, with this fund to be used for the purpose of implementing the program.

The bill would transfer $5,000,000 from the General Fund to the California Rx Plus Program Fund, thus constituting an appropriation.

Vote: ⅔. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 112 (commencing with Section 130500) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA RX PLUS STATE PHARMACY ASSISTANCE PROGRAM

CHAPTER 1. GENERAL PROVISIONS

130500. (a) This division shall be known, and may be cited, as the California Rx Plus State Pharmacy Assistance Program.

(b) For purposes of this division, the following definitions apply:

(1) "Department" means the State Department of Health Services.

(2) "Fund" means the California Rx Plus Program Fund.

(3) "Program" means the California Rx Plus State Pharmacy Assistance Program.

(4) (A) "Qualified resident" means a resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines, as updated periodically in the Federal Register by the United States Department of Health and Human Services under the authority of Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902(2)).

(B) "Qualified resident" also means a resident of the state whose family incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal 15 percent or more of family income.

(C) For purposes of this paragraph, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

130501. There is hereby established in the State Department of Health Services, the California Rx Plus State Pharmacy Assistance Program.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCEDURES

130505. (a) To be eligible for the program, an individual shall be a qualified resident, as defined in paragraph (4) of subdivision (b) of Section 130500 and shall not have outpatient prescription drug coverage paid for in whole or in part by the Medi–Cal program or the Healthy Families Program.

(b) An individual enrolled in Medicare may participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare.

130506. (a) The department shall establish application forms and procedures for enrollment in the program.

(b) In assessing the income requirement for program eligibility, the department shall use the income information reported on the application and shall not require additional documentation.

(c) Upon determination of eligibility, the department shall mail the qualified resident a California Rx Plus Discount Card.

CHAPTER 3. ADMINISTRATION AND SCOPE

130515. The department shall conduct an outreach program to inform California residents of their opportunity to participate in the California Rx Plus State Pharmacy Assistance Program. The department shall coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program.

130516. (a) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(b) Any drug manufacturer may participate in the program.

130517. (a) The amount a program participant pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the

specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer and the state's share of the discount.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130518. (a) The department shall negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program.

(b) Upon receipt of a determination from the federal Centers for Medicare and Medicaid Services that the program is a state pharmaceutical assistance program as provided in Section 130522, the department shall seek to contract for drug rebates that result in a net price lower than the Medicaid best price for drugs covered by the program.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

(d) No less than 95 percent of the drug rebates negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by participants in the program.

130519. (a) To the extent permitted by federal law, and subject to any necessary federal approvals or waivers, the department may require prior authorization in the Medi–Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) for any drug of a manufacturer that does not agree to provide rebates to the department for prescription drugs purchased under this division.

(b) The names of manufacturers that do and do not enter into rebate agreements with the department pursuant to this division shall be public information and shall be released to the public.

130520. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130521. (a) The department shall execute agreements with drug manufacturer patient assistance programs to provide a

single point of entry for eligibility determination and claims processing for drugs available through those programs.

(b) The department shall develop a system to provide a participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer patient assistance program.

(c) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the program established pursuant to this division.

(d) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30–day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(e) The California Rx Plus Discount Card issued pursuant to subdivision (c) of Section 130506 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a health benefit card.

130522. The department shall seek a determination from the federal Centers for Medicare and Medicaid Services that the program established pursuant to this division complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) and that discounts provided under the program are exempt from the Medicaid best price requirement.

130523. (a) The department shall deposit all payments the department receives pursuant to this division into the California Rx Plus Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130517 and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

(c) Notwithstanding Section 16305.7 of the Government Code, the fund shall also contain any interest accrued on moneys in the fund.

SEC. 2. The sum of five million dollars ($5,000,000) is hereby transfered from the General Fund to the California Rx Plus Program Fund, to fund the cost of implementing the California Rx Plus State Pharmacy Assistance Program established pursuant to Division 112 (commencing with Section 130500) of the Health and Safety Code.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 76 **VERSION: INTRODUCED**

AUTHOR: FROMMER **SPONSOR: FROMMER**

RECOMMENDED POSITION:

SUBJECT: OFFICE OF PHARMACEUTICAL PURCHASING

Existing Law:

1) Authorizes the Department of General Services (DGS) to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. (Govt Code 14977-14981)

2) Requires four state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. (Govt Code 14977-14981)

This Bill:

1) Repeals these provisions authorizing DGS's drug purchasing program. (Govt Code 14977-14981 Repealed)

2) Creates the Office of Pharmaceutical Purchasing within California Health and Human Services Agency to purchase prescription drugs for the following entities:

a. California Department of Corrections (CDC)

b. Department of Mental Health (DMH)

c. California Youth Authority (CYA)

d. Department of Developmental Services (DDS)

e. Department of Veterans Affairs (VA)

f. California State University (CSU)

g. Any other state agency as directed by the Governor.

h. Any state, district, county, city, municipal, or public agency governmental entity that may elect to participate in the coordinated purchasing program. (Govt Code 12803 Amended, 14572 Added)

3) Authorizes the office to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The office may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar, as permissible under federal law. (Govt Code 14571 Added)

4) Authorizes the office to appoint and contract with a pharmaceutical benefits manager (PBM) or other entity to do all of the following:

a. Negotiate price discounts, rebates, or other options that achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

b. Purchase prescription drugs for participating state, district, county, or municipal governmental entities.

c. Act as a consultant to the office. (Govt Code 14574 Added)

5) Requires the office, on or before February 1, 2007, to submit a report to the Legislature on activities that have been or will be undertaken. The report would include the following:

a. The number and a description of contracts entered into with manufacturers and suppliers of drugs including any discounts, rebates, or refunds obtained.

b. The number and a description of entities that elect to participate in the coordinated purchasing program.

c. Other options and strategies that have been or will be implemented pursuant to receive the lowest cost drugs.

d. Estimated costs and savings attributable to activities that have been or will be undertaken by the office.

(Govt Code 14576 Added)

Comment:

1) Author's Intent. The author's intent is to implement drug-purchasing recommendations made by the California Performance Review (CPR). CPR estimates that its drug purchasing proposals would result in $75 million in annual state savings.

2) Current DGS Drug Purchasing Program. DGS is responsible for procuring drugs for CDC DMH, DDS, CYA, and CSU's student health centers. DGS contracts with a vendor, McKesson Corporation, to process departmental drug orders and then distribute those orders to the departments. McKesson acquires the drugs through 1) competitively procured state contracts for generic drugs, 2) negotiated state contracts for brand-name drugs, or 3) the Massachusetts Alliance, a GPO consisting of both public and private agencies. For drugs that are not available through these methods, McKesson acquires the drugs at discounted wholesale prices.

3) LAO Report. A February 2005 Legislative Analyst Office (LAO) Report, Lowering the State's Costs for Prescription Drugs, examines how the state purchases drugs for its program recipients. The LAO report was critical of many elements in CPR's drug purchasing proposal, which are also found in AB 76. Specifically, the LAO found:

a. The use of a PBM would not benefit the state since the state already has established a drug formulary, authority to negotiate drug rebates, and usually does not purchase drugs from private pharmacies.

b. There is a limited need for a drug purchasing office given that the creation of a new office could be costly, create organizational difficulties, and provide little strategic advantage to the state over the current arrangement in which procurement duties are already largely concentrated.

Overall the LAO found the state's various drug-purchasing programs could take specific actions to improve on getting the lowest price possible for prescription drugs. Legislation would be required to implement most of the actions recommended by the LAO.

4) History.

2005	
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

ASSEMBLY BILL No. 76

Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, and Pavley)

January 3, 2005

An act to amend Section 12803 of, to add Part 5.4 (commencing with Section 14570) to, and to repeal Chapter 12 (commencing with Section 14977) of Part 5.5 of, Division 3 of Title 1 of, the Government Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 76, as introduced, Frommer. Office of Pharmaceutical Purchasing.

Existing law authorizes the Department of General Services to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. Existing law requires 4 state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. Existing law grants the Department of General Services authority with respect to contracting with a pharmaceutical benefits manager or other entity and exploring additional strategies for managing drug costs.

This bill would repeal these provisions. The bill would instead establish within the California Health and Human Services Agency the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies similar to that granted to the Department of General Services under the above-described

provisions. The bill would also, however, require the office to be the purchasing agent for additional state entities and the bill would authorize the office to conduct specified activites in order to negotiate the lowest prices possible for prescription drugs. The bill would require the office, on or before February 1, 2007, to submit a report containing specified information to certain committees of the Legislature regarding the program.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 12803 of the Government Code is amended to read:

12803. (a) The California Health and Human Services Agency consists of the following departments: Health Services; Mental Health; Developmental Services; Social Services; Alcohol and Drug Abuse; Aging; Rehabilitation; and Community Services and Development.

(b) The agency also includes the Office of Statewide Health Planning and Development and the State Council on Developmental Disabilities.

(c) The Department of Child Support Services is hereby created within the agency commencing January 1, 2000, and shall be the single organizational unit designated as the state's Title IV-D agency with the responsibility for administering the state plan and providing services relating to the establishment of paternity or the establishment, modification, or enforcement of child support obligations as required by Section 654 of Title 42 of the United States Code. State plan functions shall be performed by other agencies as required by law, by delegation of the department, or by cooperative agreements.

(d) The Office of Pharmaceutical Purchasing is hereby established within the agency and shall purchase prescription drugs for state agencies pursuant to Part 5.4 (commencing with Section 14570).

SEC. 2. Part 5.4 (commencing with Section 14570) is added to Division 3 of Title 1 of the Government Code, to read:

PART 5.4. OFFICE OF PHARMACEUTICAL PURCHASING

14570. As used in this part, "office" means the Office of Pharmaceutical Purchasing within the California Health and Human Services Agency.

14571. (a) Notwithstanding any other provision of law, the office may enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The office may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar, as permissible under federal law. Contracts entered into pursuant to this part may include price discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices.

(b) Contracts under this part shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(c) To the extent permitted by federal law, and subject to any necessary federal approvals or waivers, the State Department of Health Services may require prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) for any drug of a manufacturer that does not agree to provide rebates to the office for prescription drugs purchased under this part.

14572. (a) The office shall be the purchasing agent for prescription drugs for all of the following state entities:

(1) State Department of Health Services.
(2) Department of Corrections.
(3) State Department of Mental Health.
(4) Department of the Youth Authority.
(5) State Department of Developmental Services.
(6) Department of Veterans Affairs.
(7) California State University.
(8) Any other state agency as directed by the Governor.

(b) Any state, district, county, city, municipal, or public agency governmental entity, other than a state entity specified in subdivision (a), may elect to participate in the coordinated purchasing program.

14573. (a) In order to negotiate the lowest prices possible for prescription drugs for purposes of this part, the office may do all of the following:

(1) Establish a formulary or formularies for state programs in consultation with the affected agencies.

(2) Pursue all opportunities for the state to achieve savings through the federal 340B program, as established under Section 340B of the Public Health Service Act (42 U.S.C. Sec. 256b), including the development of cooperative agreements with entities covered under the 340B program that increase access to 340B program prices for individuals receiving presciption drugs through programs in departments described in Section 14572.

(3) Develop an outreach program to ensure that hospitals, clinics, and other eligible entities participate in the program authorized under Section 340B of the Public Health Service Act (42 U.S.C. Sec. 256b).

(b) The office, in consultation with the agencies listed in subdivision (a) of Section 14572, may investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

14574. The office may appoint and contract with a pharmaceutical benefits manager or other entity for purposes of the prescription drugs purchased under this part. The pharmaceutical benefits manager or other entity may do all of the following:

(a) Negotiate price discounts, rebates, or other options that achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

(b) Purchase prescription drugs for participating state, district, county, or municipal governmental entities.

(c) Act as a consultant to the office.

14575. The department may explore additional strategies for managing the increasing costs of prescription drugs, including, but not limited to, all of the following:

(a) Coordinating programs offered by pharmaceutical manufacturers that provide prescription drugs for free or at reduced prices.

(b) Studying the feasibility and appropriateness of including in the bulk purchasing programs entities in the private sector, including employers, providers, and individual consumers.

(c) Implementing other strategies, as permitted under state and federal law, aimed at managing escalating prescription drug prices.

14576. On or before February 1, 2007, the office shall submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been or will be undertaken pursuant to this part. The report shall include, but not be limited to, all of the following:

(a) The number and a description of contracts entered into with manufacturers and suppliers of drugs pursuant to Section 14571, including any discounts, rebates, or refunds obtained.

(b) The number and a description of entities that elect to participate in the coordinated purchasing program pursuant to subdivision (b) of Section 14572.

(c) Other options and strategies that have been or will be implemented pursuant to Sections 14573 and 14575.

(d) Estimated costs and savings attributable to activities that have been or will be undertaken pursuant to this part.

SEC. 3. Chapter 12 (commencing with Section 14977) of Part 5.5 of Division 3 of Title 1 of the Government Code is repealed.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 78 **VERSION: INTRODUCED**

AUTHOR: PAVLEY **SPONSOR: PAVLEY**

RECOMMENDED POSITION:

SUBJECT: PHARMACY BENEFIT MANAGEMENT

Existing Law:

Provides for the regulation of HMOs and the benefits they provide by the Department of Managed Health Care.

This Bill:

1) Defines "labeler" as any person who repackages prescription drugs for later sale and who has a labeler code issued by the Food and Drug Administration (FDA). (H&S 150000 Added)

2) Defines "pharmacy benefits management" as the administration or management of prescription drug benefits including:

a. the procurement of prescription drugs at a negotiated rate for dispensing,

b. the processing of prescription drug claims,

c. the administration of payments related to prescription drug claims.

(H&S 150000 Added)

3) Defines "pharmacy benefits manager" (PBM) as an entity that performs "pharmacy benefits management" as defined. (H&S 150000 Added)

4) Exempts health care service plans or health insurers if they perform pharmacy benefits management directly, or through a subsidiary, exclusively for their enrollees or insureds. (H&S 150000 Added)

5) Requires PBMs to disclose to the purchaser the following:

a. The aggregate amount of all rebates that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.

b. The nature, type, and amount of all other revenue that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.

c. Any prescription drug utilization information related to the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.

d. Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.

e. The credentials of members of any pharmacy and therapeutic committee and any direct or indirect financial relationships between committee members and the pharmaceutical industry.

f. Any arrangements with prescribers, medical groups, individual practice associations, or pharmacists that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

g. Any financial arrangements related to the provision of pharmacy benefits management to the purchaser that exist between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.

(H&S 150001Added)

6) Requires PBMs to disclose to the prospective purchaser the following:

a. The aggregate amount of all rebates that the pharmacy benefits manager estimates it will receive from pharmaceutical manufacturers in connection with prescription drug benefits related to the prospective purchaser.

b. The nature, type, and amount of all other revenue that the pharmacy benefits manager estimates it will receive from pharmaceutical manufacturers in connection with prescription drug benefits related to the prospective purchaser.

c. Any administrative or other fees charged by the pharmacy benefits manager to the prospective purchaser.

d. The credentials of members of any pharmacy and therapeutic committee and any financial relationships between committee members and the pharmaceutical industry.

e. Any arrangements with prescribing providers, medical groups, individual practice associations, or pharmacists that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

(H&S 150002 Added)

7) Requires all PBM contracts to contain the following elements:

a. The amount of the total revenues, rebates, and discounts identified in subdivisions (a) and (b) of Section 4131 and subdivisions (a) and (b) of Section 4132 that shall be passed on to the purchaser.

b. The disclosure or sale of enrollee utilization data by the pharmacy benefits manager to any person or entity other than the purchaser.

c. Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.

d. Conditions under which an audit will be conducted of the contract for pharmacy benefits management services, who will conduct the audit, and who will pay for the audit.

e. Any revenues, rebates, or discounts received by the pharmacy benefits manager directly or indirectly from entities other than manufacturers and labelers.

f. The process for development of formularies and notification of changes to formularies, and approval of those changes by the purchaser, provided that the pharmacy benefits manager meets the requirements of Sections 4135 and 4136. (H&S 150004 Added)

8) Specifies the qualifications for members of a PBM pharmacy and therapeutics committee.

(H&S 150005 Added)

9) Requires a PBM pharmacy and therapeutics committee to conduct a quarterly evaluation of the health effects of therapeutic substitution programs. (H&S 150006 Added)

10) Prohibits a PBM from substituting a different drug than the drug prescribed unless the prescriber provides an express, verifiable authorization to substitute. (B&P 4137 Added)

11) Requires a request from a PBM to a prescriber for a therapeutic substitution to contain the following information:

a. The cost savings for the purchaser, if any, that are a result of the medication substitution.

b. The difference, if any, in copayments or other out-of-pocket costs paid by the patient in order to obtain the medication.

c. The existence of any additional payments received by the pharmacy benefits manager not reflected in the cost savings to the purchaser.

d. The circumstances, if any, under which the currently prescribed medication will be covered.

e. The circumstances and extent to which, if any, related health care costs arising from the change in medications will be compensated.

f. Any known differences in potential effects on patient health and safety, including side-effects.

g. The name and title of the individual authorizing the change if the authorization by the provider is given verbally. (H&S 150007 Added)

12) Requires a PBM to provide a patient with the following information before a therapeutic substitution occurs:

a. The proposed medication and the currently prescribed medication.

b. The difference in copayments or other out-of-pocket costs paid by the patient, if any.

c. Any known differences in potential effects on patient health and safety, including side-effects, if any.

d. The circumstances, if any, under which the currently prescribed medication will be covered.

e. The cost savings for the purchaser, taking into account all discounts, rebates, or other payments that lower the cost of the medication to the purchaser.

f. The existence of any additional payments received by the pharmacy benefits manager not reflected in the cost savings to the purchaser.

g. A toll-free telephone number to communicate with the pharmacy benefits manager.

h. The circumstances and the extent to which, if any, related health care costs will be compensated. (H&S 150007 Added)

13) Requires PBMs to comply with the privacy standards in HIPAA. (H&S 150008 Added)

Comment:

1) Author's Intent. According to the author, this bill is needed to create consumer protection guidelines that PBMs must meet when doing business with California clients such as CalPERS, large employers, health plans, and union trust funds. The author notes that under this bill, PBMs will have to provide the kind of information that health plans have been disclosing for years about such matters as formulary development and name brand and generic drug

switching. The author believes that creating a more transparent market will shine a light on an industry that discloses an inadequate amount of pricing and conflict of interest information and will enable clients to make informed decisions about the type of prescriptions and benefits they select on behalf of their enrollees. According to the author, this will allow clients to take full advantage of the free market by incentivizing PBMs to compete in a fair, transparent environment for California business.

2) PBM Task Force. The board convened a task force on PBM regulation in 2003. The task force conducted a thorough evaluation of PBM practices to determine whether establishing state regulation of PBMs was necessary. The task force was unable to identify a clear need for regulation of PBMs. The task force was unable to define an existing or potential consumer harm that could be remedied by the regulation of PBMs. The areas of greatest potential concern, as expressed by participants, were related to the business and contractual relationships between PBMs and their clients (health plans, employers, trust funds, etc.) that would be best resolved by those parties in their negotiations.

3) Confused Roles. The bill confuses the roles of prescriber, pharmacist, pharmacy and PBM. The bill erroneously permits a PBM to substitute a drug after obtaining permission from the prescriber. A PBM does not have the legal authority to dispense a prescription drug much less substitute a different drug than the one prescribed. A pharmacist working in a pharmacy may substitute a different drug in the following circumstances:

a. Substituting a generic equivalent to a brand name drug.
b. Substituting a different dosage form of the prescribed drug.
c. Substituting a different drug after obtaining authorization from the prescriber.

The PBM is responsible for administering a benefit and providing payment to the pharmacy, but it is not permitted to prescribe, dispense or substitute drugs.

Because of the inappropriate use of the term "pharmacy benefits manager," the intent of section 150006(a) is unclear. The section could refer to: dispensing activity in a mail order pharmacy owned and operated by the PBM, dispensing activity in a pharmacy with which the PBM contracts with to dispense prescriptions, "therapeutic substitution" programs operated by some PBMs that utilize health care practitioners to solicit prescription changes from prescribers. The intent of this section needs to be amended to make clear and appropriate roles assigned to each party.

4) Prescribing Authority. Section 150006(e) of the bill permits the patient to reverse a substitution after it has occurred. This provision gives patients the unprecedented authority to order a dangerous drug which previously has been reserved for appropriately licensed health care professionals. The selection of a prescription drug is authorized to specific health care practitioners. Patients frequently request specific drugs from prescribers but the ultimate authority over the issuance of a prescription is held by the prescriber.

5) ERISA. As this bill affects the provision of a healthcare benefit, it may be subject to pre-emption by Employee Retirement Income Security Act (ERISA). ERISA is a federal statute governing the provision of employment benefits and its provisions can result in state regulation of benefits being invalidated. Pre-emption issues with ERISA are complex and this legislation should be reviewed by an individual with expertise in ERISA pre-emption case law to determine if it is likely to be overturned by a federal court.

6) State Legislation. AB 1960 (Pavley 2004), Pharmacy Benefit Management, was introduced last session and passed through the Legislature. Governor vetoed the bill. In his veto message the Governor stated "this measure would have the unintended consequence of increasing drug costs to health plans, the Medi-Cal Program and other purchasers, without providing any real consumer benefit. Studies, including one from the Federal Trade Commission, have shown that enactment of this legislation will limit competition and significantly increase the cost of prescription drugs."

The introduced version of AB 78 is the same as the enrolled version of AB 1960. The board took a position of "No Position" on the enrolled version of AB 1960.

7) Other States: Maine's law was the first of its kind. Shortly after passage, the law was challenged in the courts by the Pharmaceutical Care Management Association. The lawsuit claimed that Maine's Unfair Prescription Drug Practices Act is preempted by federal law, would effect a regulatory taking of trade secrets and revenues, and violates due process, freedom of speech and the Commerce Clause of the Constitution.

States that rejected PBM disclosure laws last year include California, Florida, Iowa, Kansas Maryland, Minnesota, Mississippi, New York, Vermont and Washington, the association said.

8) History.

2005	
Jan. 27	To Com. on RLS.
Jan. 18	From print. May be acted upon on or after February 17.
Jan. 14	Introduced. Read first time. To Com. on RLS. for assignment. To print.

9) Support and Opposition

List of Support and Opposition for AB 1960 (Pavley 2004)

SUPPORT

California Labor Federation, AFL-CIO (co-source)
California Alliance for Retired Americans (co-source)
American Association of Retired Persons
AIDS Healthcare Foundation
American Federation of State, County and Municipal Employees
Automotive and Allied Industries Employees of San Diego County, Teamsters Local No. 481
California Conference Board of Amalgamated Transit Union
California Conference of Machinists
California Commission on Aging
California Faculty Association
California Health Advocates
California Nurses Association
California Pharmacists Association
California Professional Firefighters
California Public Interest Research Group
California School Employees Association
California Seniors Coalition
California State Employees Association
California Teamsters Public Affairs Council
Communications Workers of America, Local 9423, District 1 & 2,
Santa Clara, San Mateo, Santa Cruz, San Benito, Monterey, San Luis Obispo
Communications Workers of America, Local 9575, Camarillo
Communications Workers of America, Local 9586, Norwalk
Congress of California Seniors
Consumer Federation of California
Consumers Union
Engineers and Scientists of California, IFPTE Local 20
Foundation for Taxpayer and Consumer Rights
Graphic Communications Union Local No. 583, San Francisco
Gray Panthers California
Health Access California

Health Care for All - California
Hotel Employees and Restaurant Employees Local No. 49, Sacramento
International Association of Bridge, Structural, Ornamental and Reinforcing Iron Workers, Local 155
International Brotherhood of Electrical Workers, Local 340
International Brotherhood of Electrical Workers, Local 551
Laborers' International Union of North America
Motion Picture Costumers, Local 705
Office and Professional Employees International Union, Local 29
Older Women's League of California
Plumbers and Steamfitters, Local 484
Professional & Technical Engineers, IFPTE Local 21
Riverside Sheriff's Association
Sacramento-Sierra Building and Construction Trades Council
San Mateo County Central Labor Council
Santa Clara and San Benito Counties Building and Construction Trades Council
Senior Action Network
Service Employees International Union
Service Employees International Union, Local 660
Southern California District Council of Laborers
Southern California Pipe Trades, District Council 16, Los Angeles
Sprinkler Fitters and Apprentices, Local 483
State Public Employees' Retirement System
Teamsters, Local 481
Teamsters, Local 853
Teamsters Warehouse Union, Local 853, San Francisco, San Mateo, Alameda, Marin, and Contra Costa Counties
United Association of Plumbers, Pipe Fitters and Sprinkler Fitters of the
U.S. Sprinkler Fitters and Apprentices Local 483, Hayward
United Food and Commercial Workers International Union, Butchers' Union Local 120, Oakland
United Food and Commercial Workers International, Local 1179, Martinez
United Food and Commercial Workers Union, Local 839, Salinas
United Steelworkers of America, District 12, Covina
United Steelworkers of America, Local 7600, Fontana, Riverside
United Teachers of Los Angeles
Warehouse, Processing & Distribution Workers' Union, Local 26
Western Center on Law and Poverty

OPPOSITION
Academy of Managed Care Pharmacy
Aetna, Inc.
Blue Cross of California
California Association of Health Plans
Caremark Rx, Inc.
California Chamber of Commerce
PacifiCare

ASSEMBLY BILL No. 78

Introduced by Assembly Member Pavley
(Coauthors: Assembly Members Bass, Chan, Evans, Frommer, Gordon, and Koretz)

January 3, 2005

An act to add Division 113 (commencing with Section 150000) to the Health and Safety Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 78, as introduced, Pavley. Pharmacy benefits management.

Existing law provides for the regulation of health care benefits.

This bill would define the term "pharmacy benefits management" as the administration or management of prescription drug benefits. The bill would also define the term "pharmacy benefits manager" as an entity that performs pharmacy benefits management. The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager's revenues and its drug formularies, and to make specified disclosures to the public upon request. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts and the provision of certain drugs. The bill would impose certain requirements on the membership of a pharmacy and therapeutics committee for a pharmacy benefits manager. The bill would also require a pharmacy benefits manager to meet certain conditions before substituting a prescribed medication.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 113 (commencing with Section 150000) is added to the Health and Safety Code, to read:

DIVISION 113. PHARMACY BENEFITS MANAGEMENT

150000. For purposes of this division, the following definitions shall apply:

(a) "Labeler" means any person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Section 207.20 of Title 21 of the Code of Federal Regulations.

(b) "Pharmacy benefits management" is the administration or management of prescription drug benefits. Pharmacy benefits management shall include all of the following: the procurement of prescription drugs at a negotiated rate for dispensation within this state, the processing of prescription drug claims, and the administration of payments related to prescription drug claims.

(c) "Pharmacy benefits manager" is any person who performs pharmacy benefits management. The term does not include a health care service plan or health insurer if the health care service plan or health insurer offers or provides pharmacy benefits management services and if those services are offered or provided only to enrollees, subscribers, or insureds who are also covered by health benefits offered or provided by that health care service plan or health insurer, nor does the term include an affiliate, subsidiary, or other related entity of the health care service plan or health insurer that would otherwise qualify as a pharmacy benefits manager, as long as the services offered or provided by the related entity are offered or provided only to enrollees, subscribers, or insureds who are also covered by the health benefits offered or provided by that health care service plan or health insurer.

(d) "Prospective purchaser" is any person to whom a pharmacy benefits manager offers to provide pharmacy benefit management services.

(e) "Purchaser" is any person who enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefit management services.

150001. A pharmacy benefits manager shall disclose to the purchaser in writing all of the following:

(a) The aggregate amount of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the purchaser.

(b) For a specified list of therapeutic classes, the aggregate amount for each therapeutic class of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the purchaser. A therapeutic class shall include at least two drugs.

(c) The nature, type, and amount of all other revenue that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the purchaser. A pharmacy benefits manager shall not be required to disclose the purchase discounts based upon invoiced purchase terms for prescription drugs purchased directly or indirectly from a pharmaceutical manufacturer or labeler for sale and distribution through the mail order pharmacy of the pharmacy benefits manager.

(d) Any prescription drug utilization information related to utilization by the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.

(e) Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.

(f) Any arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

(g) Any financial arrangements related to the provision of pharmacy benefits management to the purchaser that exist

between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.

150002. A pharmacy benefits manager shall disclose to a prospective purchaser in writing all of the following:

(a) The aggregate amount of all rebates and other retrospective utilization discounts that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager.

(b) For a specified list of therapeutic classes, the aggregate amount for each therapeutic class of all rebates and other retrospective utilization discounts that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager. A therapeutic class shall include at least two drugs.

(c) The nature, type, and amount of all other revenue that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager. A pharmacy benefits manager shall not be required to disclose the purchase discounts based upon invoiced purchase terms for prescription drugs purchased directly or indirectly from a pharmaceutical manufacturer or labeler for sale and distribution through the mail order pharmacy of the pharmacy benefits manager.

(d) Any administrative or other fees charged by the pharmacy benefits manager to the prospective purchaser.

(e) Any arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

150003. (a) A pharmacy benefits manager shall provide the information described in Section 150001 no less frequently than on a quarterly basis.

(b) Except for utilization information, a pharmacy benefits manager need not make the disclosures required in Sections 150001 and 150002 unless and until the purchaser or prospective purchaser agrees in writing to maintain as confidential any proprietary information. That agreement may provide for equitable and legal remedies in the event of a violation of the agreement. That agreement may also include persons or entities with whom the purchaser or prospective purchaser contracts to provide consultation regarding pharmacy services. Proprietary information includes trade secrets, and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers and personnel held by a pharmacy benefits manager and used for its business purposes.

150004. A pharmacy benefits manager may not execute a contract for the provision of pharmacy benefits management services that fails to address the following items:

(a) The amount of the total revenues, rebates, and discounts identified in subdivisions (a), (b), and (c) of Section 150001 and subdivisions (a), (b), and (c) of Section 150002 that shall be passed on to the purchaser.

(b) The disclosure or sale of enrollee utilization data by the pharmacy benefits manager to any person or entity other than the purchaser.

(c) Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.

(d) Conditions under which an audit will be conducted of the contract for pharmacy benefits management services, who will conduct the audit, and who will pay for the audit.

(e) Any revenues, rebates, or discounts received by the pharmacy benefits manager directly or indirectly from entities other than manufacturers and labelers that are related to the services to be provided to the purchaser.

(f) The process for development of formularies and notification of changes to formularies, and approval of those changes by the purchaser, provided that the pharmacy benefits manager meets the requirements of Sections 150005, 150006, and 150007.

(g) Whether there is a difference between the price paid to a retail pharmacy and the amount that will be billed to the purchaser for prescription drugs.

150005. (a) All members of a pharmacy and therapeutics committee for a pharmacy benefits manager shall be physicians, pharmacists, academics, or other health care professionals, and a majority of committee members shall not be employed by the pharmacy benefits manager.

(b) A pharmacy and therapeutics committee member shall not be an officer, employee, director, or agent of, or any person who has financial interest in, other than ownership of stock from open market purchases of less than a nominal amount of the outstanding stock of, pharmaceutical companies.

150006. (a) Except as provided in subdivision (b), any request from a pharmacy benefits manager to a prescriber for authorization to substitute a medication shall include all of the following disclosures:

(1) The cost savings for the purchaser, if any, that are a result of the medication substitution.

(2) The difference, if any, in copayments or other out-of-pocket costs paid by the patient in order to obtain the medication.

(3) The existence of additional payments received by the pharmacy benefits manager that are not reflected in the cost savings to the purchaser.

(4) The circumstances, if any, under which the currently prescribed medication will be covered.

(5) The circumstances and extent to which, if any, related health care costs arising from the medication substitution will be compensated.

(6) Any known differences in potential effects on a patient's health and safety, including side effects.

(b) A pharmacy benefits manager shall not be required to make the disclosures required by subdivision (a) under any of the following instances:

(1) The substitution is from a brand drug to a generic or chemical equivalent in accordance with applicable state law.

(2) The medication substitution is initiated for patient safety reasons.

(3) The currently prescribed medication is no longer available in the market.

(4) The substitution is initiated pursuant to a drug utilization review.

(5) The substitution is required for coverage reasons where the prescribed drug is not covered by the patient's formulary or plan.

(c) A pharmacy benefits manager shall record the name and title of the prescriber, or the person other than the prescriber, authorizing the medication substitution if the authorization is given verbally.

(d) The pharmacy benefits manager shall not substitute a medication for a currently prescribed medication unless the pharmacy benefits manager communicates with the patient to provide that patient or their representative the following information:

(1) The proposed medication and the currently prescribed medication.

(2) The difference in copayments or other out-of-pocket costs paid by the patient, if any.

(3) Potential side effects of the medication substitution.

(4) The circumstances, if any, under which the currently prescribed medication will be covered.

(5) The circumstances and the extent to which, if any, health care costs related to the medication substitution will be compensated.

(6) Notification that the patient may decline the medication substitution if the currently prescribed drug remains on the patient's formulary, and the patient is willing to pay any difference in the copayment amount.

(7) A toll-free telephone number to communicate with the pharmacy benefits manager.

(e) The pharmacy benefits manager shall cancel and reverse the medication substitution upon written or verbal instructions from a prescriber or the patient. The pharmacy benefits manager shall not be required to cancel and reverse the medication substitution if the prescribed drug is no longer on the purchaser's formulary or the patient is unwilling to pay a higher copayment or other cost associated with the prescribed drug.

(f) The pharmacy benefits manager shall maintain a toll-free telephone number during normal business hours for a minimum

of eight hours per day Monday through Friday for prescribers and patients.

(g) The pharmacy benefits manager shall not charge the individual any additional copayments or fees related to the replacement medication.

150007. A pharmacy benefits manager shall monitor the health effects on patients of medication substitutions requested by the pharmacy benefits manager. The pharmacy benefits manager shall, on a quarterly basis, report to his or her Pharmacy and Therapeutics Committee the results of the monitoring. This report shall include all patient and prescriber communications received by the pharmacy benefits manager that concern the efficacy or health effects of the medication substitutions.

150008. All disclosures made pursuant to this division shall comply with the privacy standards of the federal Health Insurance Portability and Accountability Act.

CORRECTIONS:

Heading — Lines 1 and 2.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 225 **VERSION: INTRODUCED**

AUTHOR: NEGRETE MCLEOD **SPONSOR: L.A. CARE HEALTH PLAN**

RECOMMENDED POSITION:

SUBJECT: ELECTRONIC PRESCRIPTION INFORMATION.

Existing Law:

1) The Federal Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("DIMA") establishing a "safe harbor" for certain health care providers and administrators to exchange "nonmonetary remuneration" under certain limitations to stimulate the use of e-prescribing.

2) State law relative to insurance fraud makes it a crime for healing arts practitioners to receive money or other consideration for, or to engage in various related activities with respect to, the referral of patients, clients, or customers to any person, with certain exceptions (B&P 650)

This Bill:

Allows a licensed health care facility, or a licensed health care professional prescribing or dispensing medication, to receive nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information. Nonmonetary remuneration includes hardware, software, information technology, and training services for purposes of facilitating the electronic transmission of prescription information.

Comment:

1) Author's Intent. The author's intent is to conform state law to applicable federal provisions so the advances in e-prescribing can take place in California without violating existing state laws. The author believes AB 225 is an initial step towards expanded e-health, and improvements in the quality and efficiency of health care in California, in a fashion consistent with national policies and goals.

2) Consumer Gain? An argument can be made that getting hardware and software for e-prescriptions writing into the hands of prescribers will benefit consumers. Genearally e-prescriptions have been thought of as a way to reduce prescription errors, but recent studies have shown that that while e-prescriptions have reduced errors, they are not error free. Consequently, increasing the number of health care professionals and pharmacies capable of writing and processing e-prescriptions should be in the consumers' interests.

AB 225 may have the unintended consequence of restricting consumer choice. Business and Professions Code section 4170 gives patients the option of obtaining a prescription for a pharmacy of their choice. If prescribers and pharmacies are given hardware and software to facilitate e-prescriptions, a health care professional that has the option of writing e-prescriptions may direct patients to specific pharmacies that have the ability to process these prescriptions

with preprogrammed connections to specific pharmacies. These pharmacies may not be the ones a consumer would choose in the absence of the prescriber influence. Additionally, software compatibility (prescribers' and pharmacys') may restrict choice to specific pharmacies again limiting a patient's freedom of choice. Pharmacies that are equipped to process e-prescriptions are likely to see a financial gain if this measure is enacted.

Who stands to gain the most if AB 225 is enacted? Prescribers, consumers, or pharmacies?

3) Other Legislation. None

4) History.

2005

Feb. 15	Referred to Com. on HEALTH.
Feb. 4	From printer. May be heard in committee March 6.
Feb. 3	Read first time. To print.

ASSEMBLY BILL No. 225

Introduced by Assembly Member Negrete McLeod

February 3, 2005

An act to amend Section 650 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 225, as introduced, Negrete McLeod. Electronic prescription information.

Existing law relative to insurance fraud makes it a crime for healing arts practitioners to receive money or other consideration for, or to engage in various related activities with respect to, the referral of patients, clients, or customers to any person, with certain exceptions.

This bill would exempt from these provisions a licensed health care facility or licensed health care professional prescribing or dispensing medication that receives nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 650 of the Business and Professions Code is amended to read:

650. Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code, the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend,

discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, clinic (including entities exempt from licensure pursuant to Section 1206 of the Health and Safety Code), or health care facility solely because the licensee has a proprietary interest or coownership in the laboratory, pharmacy, clinic, or health care facility; provided, however, that the licensee's return on investment for that proprietary interest or coownership shall be based upon the amount of the capital investment or proportional ownership of the licensee which ownership interest is not based on the number or value of any patients referred. Any referral excepted under this section shall be unlawful if the prosecutor proves that there was no valid medical need for the referral.

Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful for a licensed health care facility, or a licensed health care professional prescribing or dispensing medication, to receive nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information, as provided in Section 11164 of the Health and Safety Code. Nonmonetary remuneration includes hardware, software, information technology, and training services for purposes of facilitating the electronic transmission of prescription information.

"Health care facility" means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Health Services under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in the county jail for not more than one year, or by imprisonment in the state prison, or by a fine not exceeding fifty thousand dollars ($50,000), or by both that imprisonment and fine. A second or subsequent conviction is punishable by imprisonment in the state prison or by imprisonment in the state prison and a fine of fifty thousand dollars ($50,000).

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 283 **VERSION: INTRODUCED**

AUTHOR: KORETZ **SPONSOR: KORETZ**

RECOMMENDED POSITION:

SUBJECT: PSEUDOEPHEDRINE: RETAIL SALE

Existing Law:

1) It unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer or furnish pseudoephedrine to a person under 18 years of age. (H&S 11100(g)(1))

2) It unlawful for a person under 18 years of age to possess pseudoephedrine. (H&S 11100(g)(2))

3) It is unlawful for a retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids. (H&S 11100(g)(3))

This Bill:

1) Requires that the dispensing, sale, or distribution at retail of any compound, mixture, preparation, or product that contains any detectable quantity of pseudoephedrine, or any detectable quantity of any salt, optical isomer, or salt of an optical isomer of pseudoephedrine, shall be subject to the following requirements:

a. The sale of pseudoephedrine products be made in a California pharmacy licensed by the Board of Pharmacy.

b. The sale of pseudoephedrine products be made only by a pharmacist or pharmacy technician who is currently licensed in this state or by a pharmacy clerk under the supervision of a currently licensed pharmacist or pharmacy technician.

c. The purchaser is restricted from purchasing more than nine grams of pseudoephedrine in a within any 30 day period.

d. The purchaser of pseudoephedrine products would be required to show a government issued photo identification.

e. Before distributing or selling any pseudoephedrine product to a purchaser, a pharmacist, pharmacy technician, or a pharmacy clerk shall request government issued photo identification from the purchaser and shall obtain the following information to be recorded in a written transaction log or receipt:

    i. Date of purchase.

ii. Name and amount of product purchased.
iii. Government issuer of the photo identification.
iv. Identification number.
v. Purchaser's full name printed in legible form.
vi. Purchaser's signature.

f. A pharmacy would be required to maintain the written transaction log or receipt for at least three years from the date of purchase either in an automated data processing or manual record mode such that the information is readily retrievable and available to law enforcement upon request during the pharmacy's normal operating hours.

2) Allows the Department of Justice to adopt rules and regulations that exempt a pseudoephedrine product if the department finds that the substance is not used in the unlawful manufacture of methamphetamine or any other controlled substance.

3) Sets the following penalties for pharmacists who violate the measure:
a. A first violation of the measure would be a misdemeanor.
b. Subsequent violations and convictions would be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

4) This measure would not apply to any compound, mixture, or preparation in liquid, liquid capsule, or gel capsule form in which pseudoephedrine is not the only active ingredient.

(H&S 11100.01 Added)

Comment:

1) Author's Intent. The author's intent is to reduce the proliferation of methamphetamine (meth) user labs by limiting the availability of pseudoephedrine; an ingredient used in making meth. (A user lab is a small-scale meth production lab that supplies one to a few meth users.)

The author's district includes the City of West Hollywood, where meth has become the party drug of choice the in the gay male community. Author's staff states that a person taking meth is three times as more likely then someone not taking the drug to test positive for HIV.

2) Suggested Amendments. There may be occasions when pseudoephedrine is prescribed. Remove the restriction on quaintly of pseudoephedrine sold in a 30-day period, if the substance is dispensed under a valid prescription.

3) Enforcement. The board would be required to assume the log is maintained and could review this during routine inspections. If investigation is warranted, the Department of Justice (DOJ) would likely undertake it. The board would then determine discipline to the pharmacist and pharmacy technician after prosecution by the DOJ. However the board cannot cite and fine for this violation because it is in the Health and Safety Code.

4) Based on Oklahoma Law. AB 283 is based on Oklahoma HB 2176 (2004) which went into effect in April 2004. Law enforcement in Oklahoma hope that other states will enact similar provisions.

5) State Legislation. SB 152 (Speier) Pseudoephedrine, was introduced on February 7, 2005. SB 152 is similar to AB 283 in its attempt to restrict the sale of pseudoephedrine for illegal uses. SB 152 would require 1) the product be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a

document with specific information about the transaction. SB 152 would place these provisions in B&P 4051.1.

AB 162 (Runner 1999, C. 978) made it a misdemeanor for any retail distributor to sell more than 3 packages of a product that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or more than 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in a single transaction.

6) Federal Legislation. In January 2005, S103 and HR 314, the Combat Meth Act of 2005, were introduced in Congress. Each of these measures contains provisions similar to those in SB 283. Both Federal measures have been referred to their respective Committees on the Judiciary for hearing.

7) History.

2005	
Mar. 14	Referred to Com. on PUB. S.
Feb. 10	From printer. May be heard in committee March 12.
Feb. 9	Read first time. To print.

ASSEMBLY BILL No. 283

Introduced by Assembly Member Koretz
(Coauthor: Assembly Member Maze)
(Coauthor: Senator Margett)

February 9, 2005

An act to add Section 11100.01 to the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 283, as introduced, Koretz. Pseudoephedrine: retail sale.

(1) Under existing law, a retailer who makes an over-the-counter retail sale of pseudoephedrine is generally subject to a 3 package per transaction limitation or 9 gram per transaction limitation. Any violation of this requirement is a crime, punishable as specified.

This bill would provide that the dispensing, sale, or distribution at retail of any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine shall be subject to specified additional requirements. The transaction would be required to be made in a pharmacy located and currently licensed in this state and by a pharmacist or pharmacy technician who is currently licensed in this state. Before distributing or selling any product to a purchaser, the pharmacist, pharmacy technician, or pharmacy clerk would be required to request government issued photo identification from the purchaser and to obtain specified information to be recorded in a written transaction log or receipt. The pharmacy would be required to maintain the information for at least 3 years from the date of purchase such that the information would be readily retrievable and available to law enforcement upon request during the pharmacy's normal operating hours. A violation of any of these provisions would be a

misdemeanor, punishable as specified. By creating new crimes, this bill would impose a state-mandated local program upon local governments.

(2) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11100.01 is added to the Health and Safety Code, to read:

11100.01. (a) In addition to any requirement specified in Section 11100, the dispensing, sale, or distribution at retail of any compound, mixture, preparation, or product that contains any detectable quantity of pseudoephedrine, or any detectable quantity of any salt, optical isomer, or salt of an optical isomer of pseudoephedrine, shall be subject to the following requirements:

(1) The dispensing, sale, or distribution at retail of any product specified in subdivision (a) shall be made in a pharmacy located and currently licensed in this state.

(2) The dispensing, sale, or distribution at retail of any product specified in subdivision (a) shall be made only by a pharmacist or pharmacy technician who is currently licensed in this state or by a pharmacy clerk under the supervision of a currently licensed pharmacist or pharmacy technician.

(b) Before distributing or selling any product specified in subdivision (a) to a purchaser, a pharmacist, pharmacy technician, or a pharmacy clerk shall request government issued photo identification from the purchaser and shall obtain the following information to be recorded in a written transaction log or receipt:

(1) Date of purchase.

(2) Name and amount of product purchased.

(3) Government issuer of the photo identification.

(4) Identification number.

(5) Purchaser's full name printed in legible form.

(6) Purchaser's signature.

(c) The pharmacy shall maintain the written transaction log or receipt for at least three years from the date of purchase either in an automated data processing or manual record mode such that the information is readily retrievable and available to law enforcement upon request during the pharmacy's normal operating hours.

(d) This section shall not apply to any compound, mixture, or preparation in liquid, liquid capsule, or gel capsule form in which pseudoephedrine is not the only active ingredient.

(e) (1) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that exempt a substance from the application of subdivision (a) if the department finds that the substance is not used in the unlawful manufacture of methamphetamine or any other controlled substance.

(2) The Department of Justice shall, upon satisfactory application by the manufacturer of a drug product to the department, exempt any product the department determines to have been formulated in such a way as to effectively prevent the conversion of any active ingredient in the product into methamphetamine or any other controlled substance.

(f) (1) A first violation of this section is a misdemeanor.

(2) Any person who has previously been convicted of a violation of this section or Section 11100 shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(g) It is the intent of the Legislature that this section and Section 11100 shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing pseudoephedrine.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the

penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 288 **VERSION: INTRODUCED**

AUTHOR: MOUNTJOY **SPONSOR: SENIOR LEGISLATORS**

RECOMMENDED POSITION:

SUBJECT: PHARMACIES: PRESCRIPTION CONTAINERS: LABELS

Existing Law:

Prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled. (B&P 4076(a))

If requested by the patient, a label may list the condition for which the drug was prescribed. (B&P 4076(a)(10))

This Bill:

Revises the prescription labeling requirement to require a container to be labeled with, among other things, the "condition" for which the drug was prescribed, unless the patient, physician, or a parent or legal guardian of a minor patient requests that the information be omitted. (B&P 4076(a)(10) Amended)

Comment:

1) Author's Intent. The author intends to increase patient compliance with prescribed drug therapy. Compliance is particularly important among older persons taking numerous medications. Without indications on the label of each prescription, it is difficult for many patients to know which drug is taken for which condition. This is particularly so for those whose care is entrusted to a caregiver or family member.

2) Compliance. Patient compliance with drug therapy is a substantial problem in the health care system. In studies of patient behavior, only about half of patients who leave a physician's office with a prescription take the drug as directed. The most common reason given for noncompliance is forgetfulness, which could be actually denial of illness; having to take a drug is a constant reminder of illness. Compliance is worse with chronic diseases requiring complex, long-term treatment. Older persons may take several drugs; the regimen may be complex and hard to remember and to follow, thereby increasing the likelihood of an adverse drug interaction According to an estimate from the Office of the U.S. Inspector General, noncompliance results in 125,000 deaths from cardiovascular disease each year. If patients took their drugs as directed, up to 23% of nursing home admissions, 10% of hospital admissions, many physician visits, many diagnostic tests, and many unnecessary treatments could be avoided.

3) Board of Pharmacy Concerns. The bill requires the condition be printed on the label, unless the prescriber or patient requests it be omitted. If a prescriber omits this information on the prescription, the pharmacist will need to contact the prescriber to confirm that it was not accidentally omitted, but rather requested. This would be an additional workload for the pharmacist.

Changing the labeling requirements will result in a need to educate the prescribers of prescription medications on the change in law.

4) Other Legislation. A version of AB 288 (AB 2125, Levine 2004) was introduced last year. The author pulled the bill before its first committee hearing.

AB 657 (Karnette 2005) Pharmacies Prescription Containers Labels, a bill very similar to AB 288 has been introduced this session. AB 657 would require prescription labels to contain the "intended purpose" of the drug unless the patient receiving the drug request the information be omitted.

5) History.

2005	
Mar. 3	Referred to Coms. on HEALTH and B. & P.
Feb. 10	From printer. May be heard in committee March 12.
Feb. 9	Read first time. To print.

ASSEMBLY BILL No. 288

Introduced by Assembly Member Mountjoy

February 9, 2005

An act to amend Section 4076 of the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

AB 288, as introduced, Mountjoy. Pharmacies: prescription containers: labels.

The existing Pharmacy Law provides for the licensing, regulation, and enforcement of the practice of pharmacy by the California State Board of Pharmacy. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

The Pharmacy Law prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with, among other things, the condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription.

This bill would revise this prescription container labeling requirement to, instead, require the container to be labeled with, among other things, the condition for which the drug was prescribed, unless the patient, physician, or a parent or legal guardian of a minor patient requests that the information be omitted. By revising the definition of a crime, this bill would impose a state–mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed ~~if requested by the patient and the condition is indicated on the prescription~~, *unless the patient, physician, or a parent or legal guardian of a minor patient requests that the information be omitted.*

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized

procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 497 **VERSION: INTRODUCED**

AUTHOR: NEGRETE MCLEOD **SPONSOR: NEGRETE MCLEOD**

RECOMMENDED POSITION:

SUBJECT: DRUG WHOLESALERS AND MANUFACTURERS: LICENSURE EXEMPTION.

Existing Law:

Requires a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale is considered an out-of-state distributor that must be licensed by the board prior to engaging in those activities. (B&P 4161)

This Bill:

Exempts from the licensing requirements of B&P 4161, a person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state if that transaction is either of the following:

a. An intracompany transaction between the person and a division, subsidiary, or parent of the person; or

b. A transaction between the person and an affiliated or related company for purposes of stocking or restocking that company. (An affiliated or related company is one where the person and company are under common ownership and control of the same corporate entity.)

(B&P 4161 Amended)

Comment:

1) Author's Intent. Last year, the board sponsored AB 2628, which required among other things, that effective January 1, 2005 all wholesaler locations that ship prescription drugs into California had to be licensed with the board as nonresident wholesalers, even if shipping to a California licensed wholesaler. The sponsor believes that the current law is excessive. Given that companies track the movement and transfer of drugs from one facility to another the chances of counterfeited drugs entering the system is remote. Drug wholesalers and distributors support this view.

2) What's at Stake? Protecting the drug supply from the introduction of counterfeit drugs is paramount. No one approach will work on its own, consequently the Food and Drug Administration recommends that states take a multiple prong approach that includes: licensing wholesalers and out of state distributors; establishing a drug pedigree system; and increasing penalties for drug counterfeiters. Last year the Governor signed SB 1307 and AB 2628, which put these measures into effect.

If AB 497 is enacted the board would loose its ability to take enforcement action against unlicensed out of state distributors that ship drugs into California (if the unlicensed distributor has a subsidiary or parent company licensed by the board). This loss will weaken the state's ability to protect the safety of the drug supply.

3) Legislative History. In 2004 the board sponsored SB 1307 (Chapter 857, Statutes of 2004) Wholesalers and Manufacturers of Dangerous Drugs and Devices, and AB 2682 (Chapter 887, Statutes of 2004) Pharmacy: Out-of-State Wholesalers.

4) History.

2005

Mar. 3	Referred to Coms. on HEALTH and B. & P.
Feb. 17	From printer. May be heard in committee March 19.
Feb. 16	Read first time. To print.

ASSEMBLY BILL No. 497

Introduced by Assembly Member Negrete McLeod

February 16, 2005

An act to amend Section 4161 of the Business and Professions Code, relating to pharmacy practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 497, as introduced, Negrete McLeod. Drug wholesalers and manufacturers: licensure exemption.

Existing law, the Pharmacy Law, provides for the licensure and regulation by the California State Board of Pharmacy of pharmacies and other persons. Under that law, a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale is considered an out-of-state distributor that must be licensed by the board prior to engaging in those activities.

This bill would exempt from this licensure requirement certain intracompany transactions and transactions between affiliated or related companies, as defined.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4161 of the Business and Professions Code, as added by Chapter 887 of the Statutes of 2004, is amended to read:

4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated

representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.

(*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) ~~A pharmacy that meets the requirements of Section 4001.2, as added by Senate Bill 1149 of the 2003–04 Regular Session, including any subsequent amendment thereto, shall not be considered a nonresident wholesaler for purposes of this section.~~*The licensure requirements of this section shall not apply to a person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state if that transaction is either of the following:*

(1) An intracompany transaction between the person and a division, subsidiary, or parent of the person.

(2) A transaction between the person and an affiliated or related company for purposes of stocking or restocking that company. For purposes of this paragraph, an affiliated or related company is one where the person and company are under common ownership and control of the same corporate entity.

(n) This section shall become operative January 1, 2006.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 657 **VERSION: INTRODUCED**

AUTHOR: KARNETTE **SPONSOR: SENIOR LEGISLATORS**

RECOMMENDED POSITION:

SUBJECT: PHARMACIES: PRESCRIPTION CONTAINERS: LABELS

Existing Law:

Prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled. (B&P 4076(a))

If requested by the patient, a label may list the condition for which the drug was prescribed. (B&P 4076(a)(10))

This Bill:

Revises the prescription labeling requirement to require a container to be labeled with, among other things, the "intended purpose" for which the drug was prescribed, unless the patient, physician, or a parent or legal guardian of a minor patient requests that the information be omitted. (B&P 4076(a)(10) Amended)

Comment:

1) Author's Intent. The author intends to increase patient compliance and reduce confusion with prescribed drug therapy.

2) Confusion. Many prescription drugs have more than one use or purpose. A number of people, particularly seniors, have unexpired prescription drugs in their medicine cabinets, and do not know the intended use for the drug because it is omitted from the label. Many patients are unaware of their right to request that the prescription label contain information about the drug's purpose.

Including the purpose for the prescription drug on the prescription label may 1) reduce the number of telephone calls to doctors and pharmacists requesting information about the purpose of a prescription; 2) provide a check system between the doctor writing the prescription and the pharmacist filling the prescription; and 3) reduce medication error.

3) Board of Pharmacy Concerns. The bill requires the intended purpose for the drug being prescribed be printed on the label, unless the prescriber or patient requests it be omitted. If a prescriber omits this information on the prescription, the pharmacist would need to contact the prescriber to confirm that it was not accidentally omitted, but rather requested. This would be an additional workload for the pharmacist.

Changing the labeling requirements will result in a need to educate the prescribers of prescription medications on the change in law.

4) Other Legislation. A version of AB 288 (AB 2125, Levine 2004) was introduced last year. The author pulled the bill before its first committee hearing.

AB 288 (Mountjoy 2005) Pharmacies Prescription Containers Labels, a bill very similar to AB 657 has been introduced this session. AB 288 would require prescription labels to contain the "condition" for which a drug is prescribed unless the patient receiving the drug request the information be omitted.

5) History.

2005	
Mar. 7	Referred to Coms. on HEALTH and B. & P.
Feb. 18	From printer. May be heard in committee March 20.
Feb. 17	Read first time. To print.

ASSEMBLY BILL No. 657

Introduced by Assembly Member Karnette

February 17, 2005

An act to amend Section 4076 of the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

AB 657, as introduced, Karnette. Pharmacies: prescription containers: labels.

The existing Pharmacy Law provides for the licensing, regulation, and enforcement of the practice of pharmacy by the California State Board of Pharmacy. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

The Pharmacy Law prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with, among other things, the condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription.

This bill would eliminate the requirement of the labeling requirement pertaining to the condition for which the drug was prescribed, and would instead require the container to be labeled with the intended purpose of the drug, unless the physician who prescribes the drug or the patient receiving the drug specifically requests that the information be omitted. By revising the definition of a crime, this bill would impose a state–mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) ~~The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription~~ *The intended purpose of the drug, unless the physician who prescribes the drug or the patient receiving the drug specifically requests that the information be omitted.*

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized

procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 522 **VERSION: INTRODUCED**

AUTHOR: PLESCIA **SPONSOR: PLESCIA**

RECOMMENDED POSITION:

SUBJECT: AUTOMATED DRUG DELIVERY SYSTEM

Existing Law:

1) Provides for skilled nursing and intermediate care facilities to use an automated drug delivery system to store and distribute drugs, and to track the movement of drugs into and out of the system. (H&S 1261.6)

2) Regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system. (H&S 1261.6)

This Bill:

Clarifies existing law by:

1. Defining "pharmacy services" as the provision of both routine and emergency drugs and biologicals to meet the needs of the patient.

2. Requiring a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions when an automated drug delivery system is used.

3. Limiting access by licensed personnel to an automated drug delivery system to the prescribed drug authorized by the pharmacist and specific to the patient.

(H&S 1261.6 Amended)

Comment:

1) Author's Intent. The author's intent is to provide clean-up language for AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises. This language was requested by the Department of Health Services.

4) Legislative History. AB 2184 (Chapter 342, Statutes of 2004), Automated Dispensing Devises, expanded the use of automated drug delivery system in skilled nursing facilities. The board supported AB 2184.

5) History.

2005

Mar. 7	Referred to Coms. on HEALTH and B. & P.
Feb. 18	From printer. May be heard in committee March 20.
Feb. 17	Read first time. To print.

ASSEMBLY BILL No. 522

Introduced by Assembly Member Plescia

February 16, 2005

An act to amend Section 1261.6 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 522, as introduced, Plescia. Automated drug delivery system.

Existing law provides for skilled nursing and intermediate care facilities to use an automated drug delivery system to store and distribute drugs, and to track the movement of drugs into and out of the system. Existing law regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system.

This bill would clarify existing law to define pharmacy services and to require a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions. This bill would further clarify existing law to prevent licensed personnel from accessing a different drug or dose of a drug than that approved by a pharmacist.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 1261.6 of the Health and Safety Code is amended to read:

1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other

than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. *The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.*

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all *transactions which will include all* users accessing the system and all drugs *added to or* removed from the system.

(6) ~~When a pharmacist releases drugs for removal from the automated drug delivery system pursuant to paragraph (2), the automated drug delivery system shall not provide facility staff with access to drugs different from those released.~~ *After the pharmacist reviews and approves the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the prescribed drug authorized by the*

pharmacist and specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall only have access to the drug ordered for that scheduled time of administration.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets or drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 896 **VERSION: INTRODUCED**

AUTHOR: MATTHEWS **SPONSOR: CPHA**

RECOMMENDED POSITION:

SUBJECT: CLINICAL LABORATORIES

Existing Law:

1) Permits a physician or a person licensed as a clinical laboratory director to act as a clinical laboratory director. (B&P 1209)

2) Requires clinical laboratory directors to meet the requirements established by the federal Clinical Laboratory Improvement Amendments (CLIA). (B&P 1209)

3) Requires the clinical laboratory director to be responsible for the operation of the clinical laboratory including:

- administration
- selecting and supervising laboratory procedures
- reporting laboratory test results
- ensuring compliance with CLIA
- supervising laboratory personnel

4) Defines "routine patient assessment procedures" as a procedures that a patient could, with or without a prescription, perform for himself or herself, or clinical laboratory tests that are classified as waived pursuant to CLIA. (B&P 4052.1)

This Bill:

1) Permits a pharmacist to serve as a laboratory director when:
   a) The laboratory is only conducting laboratory tests that a pharmacist may perform under existing law.
   b) The pharmacist has completed a training program on the duties and responsibilities of a laboratory director for a clinical laboratory performing tests classified as "waived" under CLIA.
   c) The clinical laboratory possesses a certificate of waiver under CLIA.

(B&P 1209.2 Added)

2) The tests that can be preformed are:
   a) Procedures that a patient could, with or without a prescription, perform for himself or herself.
   b) Clinical laboratory tests that are classified as waived under CLIA.

3) Requires the pharmacist performing laboratory tests to report the results to both the patient and any physician specified by the patient.

(B&P 4052.1 Amended)

Comment:

1) Author's Intent. The bill was introduced to permit pharmacists to perform waived tests in a pharmacy without an outside laboratory director. The sponsor further indicates, that by permitting pharmacists to perform waived tests in a pharmacy, patients will have better access to tests required to appropriately manage their drug therapy.

The author has also introduced AB 1370 this session, which would accomplish the same goal as AB 896. After some reflection, the author has decided to drop AB 1370 and put efforts into AB 896.

2) CLIA?. Prior to 1988, less that 10% of all clinical laboratories were required to meet quality standards. Approximately 12,000 hospitals and independent laboratories were regulated under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) and the Medicare and Medicaid programs. Congressional hearings revealed serious deficiencies in quality in physician office laboratories and in Pap smear testing. Studies have demonstrated that laboratories meeting minimum personnel and quality requirements perform better than those that do not. CLIA '88 was passed to provide assurance to the public that access to safe, accurate laboratory testing is available.

Currently, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), all 150,000 clinical laboratories, including physician office laboratories, are regulated to ensure the quality of test results.

The CLIA '88 regulation unified and replaced past standards with the single set of requirements that apply to laboratory testing of human specimens. Standards for laboratory personnel, quality control and quality assurance are based on test complexity and potential harm to the patient.

3) Complexity. Determining which CLIA '88 standards apply to a test depends upon the level of complexity of that test. Three categories of testing complexity have been defined under CLIA '88. They are waived, moderate and high. One reason the tests are placed into categories is to reduce the burden of regulation for those laboratories performing tests for which a low probability of an erroneous result exists. For example, there are no personnel or inspection requirement for the waived category of testing. In addition, 75% of all tests falls within the moderate complexity category which permits an individual with only a high school degree and appropriate training to perform these tests.

4) California CLIA. CLIA permits a state with stricter clinical laboratory standards to obtain an exemption from federal regulation (and fees) if the lab tests and personnel that would be subject to CLIA are regulated by that state's clinical lab law.

Prior to the enactment of the CLIA, California already had an extensive administrative scheme for regulating clinical labs and lab personnel. However, that state law was not, in all respects, equal to or greater in regulatory oversight coverage to CLIA. Consequently, in 1995 the Legislature enacted SB 113 to bring California's clinical lab law into compliance with all of CLIA's requirements so that California could obtain a waiver from CLIA and continue to regulate its clinical labs at the state level.

One of the key components of CLIA and state clinical lab law was the requirement that clinical labs be overseen by a lab director who would be responsible for the quality control of the testing and the competency and training of the personnel who were conducting the tests. Besides a licensed physician, California law permits other persons, a licensed bioanalyst or a clinical chemist to qualify as a lab director.

5) Legislative History. AB 896 is similar to AB 1460 (Nation 2003), Laboratory Directors. The board supported this bill. AB 1460 died in its first committee hearing.

6) Related Legislation. AB 1370 (Matthews 2005), Clinical Laboratory Directors: Pharmacists, would amend B&P 1209, to redefine a laboratory director to include a pharmacist if the clinical laboratory test or examination is a routine patient assessment procedure. The authors office has stated that the author plans to drop this bill since it would accomplish the same thing as AB 896.

7) History.

2005	
Mar. 7	Referred to Coms. on B. & P. and HEALTH
Feb. 20	From printer. May be heard in committee March 22.
Feb. 18	Read first time. To print.

ASSEMBLY BILL No. 896

Introduced by Assembly Member Matthews

February 18, 2005

An act to amend Section 4052.1 of, and to add Section 1209.2 to, the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

AB 896, as introduced, Matthews. Clinical laboratories.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Under that law, a pharmacist is authorized to perform skin puncture in the course of routine patient assessment procedures or specified clinical laboratory testing. Existing law providing for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services, requires that these functions be performed under the supervision of a laboratory director, as defined. Under existing law, a violation of the provisions regulating clinical laboratories and their personnel is a crime.

This bill would authorize a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures, as defined, under specified conditions.

Because a pharmacist acting in this capacity without satisfying the designated criteria would violate the provisions regulating clinical laboratories, and would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1209.2 is added to the Business and Professions Code, to read:

1209.2. Notwithstanding any other provision of law, a pharmacist may serve as a laboratory director, as described in Section 1209, in a clinical laboratory that provides routine patient assessment procedures, as defined in Section 4052.1, if both of the following conditions are satisfied:

(a) The pharmacist has completed a training program on the duties and responsibilities of a laboratory director for a clinical laboratory performing tests classified as "waived" under CLIA.

(b) The clinical laboratory possesses a certificate of waiver under CLIA.

SEC. 2. Section 4052.1 of the Business and Professions Code is amended to read:

4052.1. *(a)* Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means *either of the following*: ~~(a) procedures~~

(1) Procedures that a patient could, with or without a prescription, perform for himself or herself~~, or (b) clinical~~.

(2) Clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal ~~Health Care Financing Administration~~ *Centers for Medicare and Medicaid Services*, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. ~~A~~

(b) A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. ~~Any~~

(c) A pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 1370 **VERSION: INTRODUCED**

AUTHOR: MATTHEWS **SPONSOR: CPHA**

RECOMMENDED POSITION:

SUBJECT: LABORATORY DIRECTORS

Existing Law:

1) Permits a physician or a person licensed as a clinical laboratory director to act as a clinical laboratory director. (B&P 1209)

2) Requires clinical laboratory directors to meet the requirements established by the federal Clinical Laboratory Improvement Amendments (CLIA). (B&P 1209)

3) Requires the clinical laboratory director to be responsible for the operation of the clinical laboratory including:

- administration
- selecting and supervising laboratory procedures
- reporting laboratory test results
- ensuring compliance with CLIA
- supervising laboratory personnel

4) Defines "routine patient assessment procedures" as a procedures that a patient could, with or without a prescription, perform for himself or herself, or clinical laboratory tests that are classified as waived pursuant to CLIA. (B&P 4052.1)

This Bill:

Redefines a "laboratory director" to include a pharmacist if the clinical laboratory test or examination is a routine patient assessment procedure. (B&P 1209 Amended)

Comment:

1) Author's Intent. The bill was introduced to permit pharmacists to perform waived tests in a pharmacy without an outside laboratory director. The sponsor further indicates, that by permitting pharmacists to perform waived tests in a pharmacy, patients will have better access to tests required to appropriately manage their drug therapy.

The author has also introduced AB 896 this session, which would accomplish the same goal as AB 1370. After some reflection, the author has decided to drop AB 1370 and put efforts into AB 896.

2) CLIA?. Prior to 1988, less that 10% of all clinical laboratories were required to meet quality standards. Approximately 12,000 hospitals and independent laboratories were regulated under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) and the Medicare and Medicaid programs. Congressional hearings revealed serious deficiencies in quality in physician office laboratories and in Pap smear testing. Studies have demonstrated that laboratories meeting

minimum personnel and quality requirements perform better than those that do not. CLIA '88 was passed to provide assurance to the public that access to safe, accurate laboratory testing is available.
Currently, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), all 150,000 clinical laboratories, including physician office laboratories, are regulated to ensure the quality of test results.

The CLIA '88 regulation unified and replaced past standards with the single set of requirements that apply to laboratory testing of human specimens. Standards for laboratory personnel, quality control and quality assurance are based on test complexity and potential harm to the patient.

3) Complexity. Determining which CLIA '88 standards apply to a test depends upon the level of complexity of that test. Three categories of testing complexity have been defined under CLIA '88. They are waived, moderate and high. One reason the tests are placed into categories is to reduce the burden of regulation for those laboratories performing tests for which a low probability of an erroneous result exists. For example, there are no personnel or inspection requirement for the waived category of testing. In addition, 75% of all tests falls within the moderate complexity category which permits an individual with only a high school degree and appropriate training to perform these tests.

4) California CLIA. CLIA permits a state with stricter clinical laboratory standards to obtain an exemption from federal regulation (and fees) if the lab tests and personnel that would be subject to CLIA are regulated by that state's clinical lab law.

Prior to the enactment of the CLIA, California already had an extensive administrative scheme for regulating clinical labs and lab personnel. However, that state law was not, in all respects, equal to or greater in regulatory oversight coverage to CLIA. Consequently, in 1995 the Legislature enacted SB 113 to bring California's clinical lab law into compliance with all of CLIA's requirements so that California could obtain a waiver from CLIA and continue to regulate its clinical labs at the state level.

One of the key components of CLIA and state clinical lab law was the requirement that clinical labs be overseen by a lab director who would be responsible for the quality control of the testing and the competency and training of the personnel who were conducting the tests. Besides a licensed physician, California law permits other persons, a licensed bioanalyst or a clinical chemist to qualify as a lab director.

5) Legislative History. AB 1460 (Nation 2003), Laboratory Directors, would have authorized a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures. The board supported this bill. AB 1460 died in its first committee hearing.

6) Related Legislation. AB 896 (Mathews 2005), Clinical Laboratories, is similar to AB 1460, and would allow a pharmacist to serve as laboratory director of a clinical laboratory that provides routine patient assessment procedures.

7) History.

2005	
Feb. 25	From printer. May be heard in committee March 27.
Feb. 22	Read first time. To print.

ASSEMBLY BILL No. 1370

Introduced by Assembly Member Matthews

February 22, 2005

An act to amend Section 1209 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 1370, as introduced, Matthews. Clinical laboratory director: pharmacists.

Existing law provides for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services and makes a violation of those provisions a crime. Existing law defines various terms for this purpose, including "laboratory director."

This bill would include a pharmacist within the definition of laboratory director if the clinical laboratory test or examination is a routine patient assessment procedure, as defined. Because a failure of such a pharmacist to comply with this particular limitation or with the provisions regulating clinical laboratories and their personnel would be punishable as a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1209 of the Business and Professions Code is amended to read:

1209. (a) As used in this chapter, "laboratory director" means any person who is a duly licensed physician and surgeon, or is licensed to direct a clinical laboratory under this chapter and who substantially meets the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory. *"Laboratory director" also means a pharmacist if the clinical laboratory test or examination is a routine patient assessment procedure, as defined in Section 4052.1.* The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

(b) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to assure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.

(c) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the

adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

(d) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether

consultant, supervisor, or director review is required prior to the individual reporting patient test results.

(e) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

(B) Monitoring the recording and reporting of test results.

(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(D) Direct observation of performance of instrument maintenance and function checks.

(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(f) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high quality service.

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(g) Subdivision (f) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 19 **VERSION: AMENDED JAN 6, 2005**

AUTHOR: ORTIZ **SPONSOR: GOVERNOR**

RECOMMENDED POSITION:

SUBJECT: California Rx Program

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California State Pharmacy Assistance Program (Cal Rx, program) within the Department of Health Services (DHS). (H&S 130600 Added)

2. Permits DHS to contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. (H&S 130602 Added)

3. Defines the terms: benchmark price, Cal Rx, fund, inpatient, lowest commercial price, manufacturer, manufacturers rebate, prescription drug, private discount drug program, recipient, resident, and third-party vendor. (H&S 130600 Added)

4. Establishes eligibility criteria for the program as:

   a. A resident of California who has a family income does not exceed 300 percent of the federal poverty guidelines. (2005 - $28,710 for an individual and $58,050 for a family of four)

   b. A family that does not have outpatient perscribtion drug coverage.

   (H&S 130605Added)

5. Set a yearly fee of $15 for application or reapplication for the program. (H&S 130606 Added)

6. Requires DHS or third party vendor to establish a Web site and call center to use for applying for the program. Additionally requires DHS or third party vendor to determine eligibility for the program within four hours of receipt of a completed application. (H&S 130606 Added)

7. Permits DHS to conduct an outreach program to inform California residents of their opportunity to participate in program, if funds are available. (H&S 130615 Added)

8. Requires DHS or third party vendor to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. (H&S 130618 Added)

9. Sets the amount a recipient pays for a drug within program as equal to the pharmacy contract rate, plus a dispensing fee that shall be negotiated by DGS, less the applicable manufacturers rebate. (H&S 130616 Added)

10. Permits DHS to terminate Cal Rx if the department makes any one of the following determinations:

a) That there are insufficient discounts to participants to make Cal Rx viable.

b) That there are an insufficient number of applicants for Cal Rx.

c) DGS is unable to find a responsible third-party vendor to administer Cal Rx. (H&S 130624 Added)

Comment:

1) Author's Intent. This bill is sponsored by the Governor and is in response to last year's veto of SB 1149 (Ortiz 2004). In his veto message the Governor stated, "A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians. California Rx represents an approach that harnesses the purchasing power of low-income seniors and uninsured Californians up to 300% of the federal poverty level ($28,710 for an individual and $58,050 for a family of four) to secure meaningful discounts in prescription drug costs. My Administration has begun negotiations with pharmaceutical companies regarding their participation in California Rx."

A fact sheet issued by the author's office states "In addition to the discounted drugs available to Cal Rx participants, Governor Schwarzenegger has secured a commitment from the Pharmaceutical Researchers and Manufacturers Association (PhRMA) to provide $10 million over the next two fiscal years to fund a clearinghouse to publicize and help Californians enroll in manufacturers' free and discount programs. The clearinghouse will provide Internet access and a toll-free multi-lingual call center to help thousands of Californians receive prescription drugs absolutely free, thereby saving them hundreds of millions of dollars per year. This element of the program does not require legislation and will begin operating in Spring 2005."

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation. AB 74 (Gordon and Frommer) California Rx Prescription Drug Hotline. This measure would require DHS to establish a drug hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

AB 73 (Frommer, Chan) Safe and Affordable Drug Importation from International Pharmacies, would require DHS to set up a web site that would provide information on importing drugs from international pharmacies.

AB 75 (Frommer) Pharmaceutical assistance program, establishes the California Rx Plus State Pharmacy Assistance Program within DHS. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. The measure stablishes eligibility for the program for families with incomes equal to or less than 400 percent of the federal poverty guidelines.

AB 76 (Frommer) Office of Pharmaceutical Purchasing. This measure would instead establish within the California Health and Human Services Agency, the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies. The bill would authorize the office to conduct specified activates in order to negotiate the lowest prices possible for prescription drugs.

5) Support / Opposition.

Support: AARP
California Medical Association
California Pharmacists Association
AIDS Healthcare Foundation
Parkinson's Action Network
American Academy of Pediatrics
California Chamber of Commerce
Northeastern California Chapter, California Arthritis Foundation Council
California Academy of Family Physicians
California Council of the Alzheimer's Association
California Psychiatric Association
Mental Health Association in California
California Hepatitis C Task Force
Epilepsy Foundation of Nor. California

Hemophilia Foundation of No. California
American College of Obstetricians and Gynecologists

Opposition: California Labor Federation
California Alliance for Retired Americans

5) History.

2005	
Mar. 17	Set for hearing April 13.
Jan. 27	To Com. on HEALTH.
Jan. 6	To Com. on RLS. From committee with author's amendments. Read second time. Amended. Re-referred to committee.
2004	
Dec. 7	From print. May be acted upon on or after January 6.
Dec. 6	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE JANUARY 6, 2005

SENATE BILL No. 19

Introduced by Senator Ortiz
(Principal coauthor: Senator Poochigian)

December 6, 2004

An act to add Division ~~113~~ *112* (commencing with Section 130600) to the Health and Safety Code, relating to ~~prescription drugs~~ *pharmacy assistance* , and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as amended, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi–Cal program, and is authorized, among other things, to enter ~~in to~~ *into* contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufactures are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California ~~Rx Program, to be administered by~~ *Pharmacy Assistance Program (Cal Rx) under the oversight of* the department. The bill would authorize the department to *implement and administer Cal Rx through a contract with a 3rd–party vendor or utilizing existing health care service provider enrollment and payment mechanisms. The bill would require the department or 3rd–party vendor to attempt to* negotiate drug rebate agreements *for Cal Rx* with drug manufacturers ~~to provide for program drug discounts~~. The bill would authorize any licensed pharmacy ~~or~~ *and any* drug manufacturer *, as defined,* to provide services under ~~the program~~ *Cal Rx* . The bill would establish eligibility criteria and application procedures for California residents to participate in ~~the program~~ *Cal Rx. The application process would*

require an applicant to attest to information provided under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program. The bill would authorize the department to terminate the program if any one of 3 determinations are made .

The bill would establish the California ~~Rx~~ *State Pharmacy Assistance* Program Fund ~~, as a continuously appropriated fund,~~ into which all payments ~~directly~~ received under ~~the program~~ *Cal Rx* would be deposited. *The bill would continuously appropriate the fund to the department for purposes of Cal Rx.*

~~The bill would appropriate $3,000,000 from the State Treasury to the department to fund staff and contract costs for the program.~~

~~The Pharmacy Law is administered by the California State Board of Pharmacy in the Department of Consumer Affairs.~~

~~This bill would require the Department of Consumer Affairs to implement, as a part of the California Rx Program that would be established under the bill, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering prescription drug costs.~~

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: ⅔. Appropriation: yes. Fiscal committee: yes. State-mandated local program: ~~no~~.

The people of the State of California do enact as follows:

~~SECTION 1. Division 113 (commencing with Section 130600) is added to the Health and Safety Code, to read:~~

SECTION 1. Division 112 (commencing with Section 130600) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (CAL RX)

CHAPTER 1. GENERAL PROVISIONS

130600. This division shall be known, and may be cited, as the California State Pharmacy Assistance Program or Cal Rx.

130601. For the purposes of this division, the following definitions shall apply:

(a) "Benchmark price" means the price for an individual drug or aggregate price for a group of drugs offered by a manufacturer equal to the lowest commercial price for the individual drug or group of drugs.

(b) "Cal Rx" means the California State Pharmacy Assistance Program.

(c) "Department" means the State Department of Health Services.

(d) "Fund" means the California State Pharmacy Assistance Program Fund.

(e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.

(f) (1) "Lowest commercial price" means the lowest purchase price for an individual drug, including all discounts, rebates, or free goods, available to any wholesale or retail commercial class of trade in California.

(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.

(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.

(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.

(g) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(h) "Manufacturers rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(i) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(j) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third–party payer program.

(k) "Recipient" means a resident that has completed an application and has been determined eligible for Cal Rx.

(l) "Resident" means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.

(m) "Third–party vendor" means a public or private entity with whom the department contracts pursuant to subdivision (b) of Section 130602, which may include a pharmacy benefit administration or pharmacy benefit management company.

130602. (a) There is hereby established the California State Pharmacy Assistance Program or Cal Rx.

(b) The department shall provide oversight of Cal Rx. To implement and administer Cal Rx, the department may contract with a third–party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi–Cal program's fiscal intermediary.

(c) Any resident may enroll in Cal Rx if determined eligible pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS

130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty

guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third–party payer.

(B) The Medi–Cal program.

(C) The children's health insurance program.

(D) The disability medical assistance program.

(E) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare.

(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:

(A) The third–party payer that paid all or part of the coverage filed for bankruptcy under the federal bankruptcy laws.

(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001), as amended.

(C) The individual is no longer eligible for the Medi–Cal program, children's health insurance program, or disability medical assistance program.

(b) Application and an annual reapplication for Cal Rx shall be made pursuant to subdivision (d) of Section 130606. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

130606. (a) The department or third–party vendor shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx.

(b) The application, at a minimum, shall do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable under penalty of perjury.

(4) Specify that the application and annual reapplication fee due upon submission of the applicable form is fifteen dollars ($15).

(c) In assessing the income requirement for Cal Rx eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx, through a Web site or call center staffed by trained operators approved by the department, or through the third–party vendor. A pharmacy, physician office, clinic, or third–party vendor completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a recipient.

(e) The department or third–party vendor shall utilize a secure electronic application process that can be used by a pharmacy, physician office, or clinic, by a Web site, by a call center staffed by trained operators, or through the third–party vendor to enroll applicants in Cal Rx.

(f) During normal hours, the department or third–party vendor shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department or third–party vendor shall mail the recipient an identification card no later than four days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department or third–party vendor may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to Cal Rx.

130607. (a) The department or third–party vendor shall attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.

(b) (1) Private discount drug programs may require an applicant to provide additional information, beyond that required by Cal Rx, to determine the applicant's eligibility for discount drug programs.

(2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, private discount drug programs in order to participate in Cal Rx.

(3) Notwithstanding paragraph (2), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.

(c) For those drugs available pursuant to subdivision (a), the department or third–party vendor shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private discount drug programs.

(d) The recipient identification card issued pursuant to subdivision (g) of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130615. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about Cal Rx and private drug discount programs available through the single point of entry as specified in subdivisions (a) and (d) of Section 130607. No outreach material shall contain the name or likeness of a drug. The name of the organization sponsoring the material pursuant to subdivision (b) may appear on the material once and in a font no larger than 10 point.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform

residents about Cal Rx. Neither Section 11005 of the Government Code, nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans. Outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.

(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

130616. (a) Any pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of the Business and Professions Code may participate in Cal Rx.

(b) Any manufacturer, as defined in subdivision (g) of Section 130601, may participate in Cal Rx.

130617. (a) This division shall apply only to prescription drugs dispensed to noninpatient recipients.

(b) The amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate pursuant to subdivision (c), plus a dispensing fee that shall be negotiated as part of the rate pursuant to subdivision (c), less the applicable manufacturers rebate.

(c) The department or third–party vendor may contract with participating pharmacies for a rate other than the pharmacist's usual and customary rate. However, the department must approve the contracted rate of a third–party vendor.

(d) The department or third–party vendor shall provide a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of subdivision (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in

Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8(g)).

(e) The department or third–party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received.

(f) The department or third–party vendor shall develop a program to prevent the occurrence of fraud in Cal Rx.

(g) The department or third–party vendor shall develop a mechanism for recipients to report problems or complaints regarding Cal Rx.

130618. (a) In order to secure the discount required pursuant to subdivisions (b) and (c) of Section 130617, the department or third–party vendor shall attempt to negotiate drug rebate agreements for Cal Rx with drug manufacturers.

(b) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

(8) Permit a manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a recipient's health information.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available within Cal Rx.

(d) The entire amount of the drug rebates negotiated pursuant to this section shall go to reducing the cost to Cal Rx recipients of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.

(e) The department or third–party vendor may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

(f) Drug rebate contracts negotiated by the third–party vendor shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or Cal Rx recipients.

(g) The third–party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to subdivision (e) of Section 130617. The department shall develop a system to prevent diversion of funds collected by the third–party vendor.

130619. (a) The department or third–party vendor shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A Summary of the problems or complaints reported regarding Cal Rx.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130620. (a) The department or third–party vendor shall deposit all payments received pursuant to Section 130618 into the California State Pharmacy Assistance Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, moneys in the fund are hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering Cal Rx. Notwithstanding any other provision of law, no money in the fund

is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

130621. The department may hire any staff needed for the implementation and oversight of Cal Rx.

130622. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) and that discounts provided under the program are exempt from Medicaid best price requirements.

130623. (a) Contracts and change orders entered into pursuant to this division and any project or systems development notice shall be exempt from all of the following:

(1) The competitive bidding requirements of State Administrative Manual Management Memo 03–10.

(2) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(3) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.

(b) Change orders entered into pursuant to this division shall not require a contract amendment.

130624. The department may terminate Cal Rx if the department makes any one of the following determinations:

(a) That there are insufficient discounts to participants to make Cal Rx viable.

(b) That there are an insufficient number of applicants for Cal Rx.

(c) That the department is unable to find a responsible third–party vendor to administer Cal Rx.

130625. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes

the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

All matter omitted in this version of the bill appears in the bill as introduced in Senate, December 6, 2004 (JR11)

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 152 **VERSION: INTRODUCED**

AUTHOR: SPEIER **SPONSOR: SPEIER**

RECOMMENDED POSITION:

SUBJECT: PSEUDOEPHEDRINE

Existing Law:

1) It unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer or furnish pseudoephedrine to a person under 18 years of age. (H&S 11100(g)(1))

2) It unlawful for a person under 18 years of age to possess pseudoephedrine. (H&S 11100(g)(2))

3) It is unlawful for a retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids. (H&S 11100(g)(3))

This Bill:

1) Requires that only a pharmacist or pharmacy technician furnish a product containing any amount of pseudoephedrine, or the salts, isomers, or salts of isomers of pseudoephedrine. (B&P 405.1 Added)

2) Requires a pharmacist to store pseudoephedrine products in a locked area within view of the pharmacist and that the pharmacist and all persons with access to the locked storage area prevent the theft or diversion of pseudoephedrine products. (B&P 405.1 Added)

3) Restricts the purchase of an individual to no more than nine grams of pseudoephedrine in a within any 30 day period. (B&P 405.1 Added)

4) Requires the purchaser of pseudoephedrine products to produce a valid California drivers license, or other valid identification containing a photograph, and for the person to sign a document indicating the date of purchase, receipt, or acquisition of the amount of product involved in the transaction. (B&P 405.1 Added)

5) Exempts from the requirements of the bill a compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. (B&P 405.1 Added)

Comment:

1) Author's Intent. The author is seeking to limit the supply of pseudoephedrine available for illegal methamphetamine (meth) production, while making the product reasonably accessible for legitimate use.

2) Enforcement. The board would be charged with enforcing these provisions because the provisions are added to Pharmacy Law. However, enforcement would likely be done by law enforcement who investigate origin of supplies for meth labs. The board would then discipline the pharmacist and pharmacy technician after prosecution by the DOJ.

Moreover the bill does not require that the pharmacy do anything wit the written document for this OTC product that is not regulated by pharmacy provisions requiring 3-year retention.

4) State Legislation. AB 283 (Koretz), Pseudoephedrine: retail sale, is similar to SB 152 in its attempt to restrict the sale of pseudoephedrine for illegal uses. AB 283 would require 1) the product be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) the purchaser produce photo identification; 3) a pharmacist or pharmacy technician to write specific information about the transaction in a transaction log or receipt; and 4) the pharmacy to maintain the information for at least 3 years. AB 283 would place these provisions in H&SC 11100.01.

AB 162 (Runner 1999, C. 978) made it a misdemeanor for any retail distributor to sell more than 3 packages of a product that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or more than 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in a single transaction.

5) Federal Legislation. In January 2005, S103 and HR 314, the Combat Meth Act of 2005, were introduced in Congress. Each of these measures contains provisions similar to those in SB 283. Both Federal measures have been referred to their respective Committees on the Judiciary for hearing.

6) History.

2005	
Feb. 24	To Com. on B., P. & E.D.
Feb. 8	From print. May be acted upon on or after March 10.
Feb. 7	Introduced. Read first time. To Com. on RLS. for assignment. To print

SENATE BILL No. 152

Introduced by Senator Speier

February 7, 2005

An act to add Section 4051.1 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 152, as introduced, Speier. Pseudoephedrine.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies and pharmacists by the California State Board of Pharmacy. That law authorizes a pharmacist to furnish and dispense prescription drugs. A knowing violation of the Pharmacy Law is a misdemeanor.

This bill would prohibit, subject to specified exceptions, the furnishing of a product containing pseudoephedrine by other than a pharmacist or pharmacy technician in a pharmacy. The bill would limit the amount of the product that a person could acquire in a 30day period and would impose requirements on acquisition.

Because the bill would specify additional requirements under the Pharmacy Law, the violation of which is a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4051.1 is added to the Business and Professions Code, to read:

4051.1. (a) A product containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine shall be furnished only by a pharmacist or pharmacy technician in a pharmacy.

(b) Notwithstanding Section 11100 of the Health and Safety Code, no person shall purchase, receive, or otherwise acquire more than nine grams of the product described in subdivision (a) within any 30-day period. Before purchasing, receiving, or otherwise acquiring a product described in subdivision (a), a person shall produce a valid California driver's license or other valid identification containing a photograph of the person and showing his or her date of birth. The person shall sign a written document, as specified by the Attorney General, indicating the date of the purchase, receipt, or acquisition and the amount of the product involved in the transaction.

(c) The pharmacist shall store the product described in subdivision (a) in a locked area within the view of the pharmacist. The pharmacist and all persons with access to the locked storage area shall prevent the theft or diversion of the product.

(d) (1) This section shall not apply to a compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension in a matrix of glycerine, polyethylene glycol, propylene glycol, and other liquid substances. "Active ingredient" includes the matrix found in liquid capsules. Regardless of the product manufacturer's labeling, a gelatin-covered solid is a gel capsule for purposes of this subdivision.

(2) The exception in paragraph (1) shall not apply to a liquid preparation that is discovered in an illegal laboratory, that is associated with an illegal laboratory, or that is any form other than one manufactured and sold by a manufacturer for medicinal purposes.

(e) This section does not apply to a substance furnished pursuant to a valid prescription.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 380 **VERSION: INTRODUCED**

AUTHOR: ALQUIST **SPONSOR: SENIOR CITIZENS, SO. CAL**

RECOMMENDED POSITION:

SUBJECT: DRUGS: ADVERSE EVENT REPORTING

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufactures to report adverse drug reactions.

This Bill:

1) Requires a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report serious adverse drug events that they observe to the FDA's MedWatch program.

2) Requires the report to be made using FDA 3500, Voluntary form.

3) Defines a serious adverse drug events as, adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

(H&S 111657 Added)

Comment:

1) Author's Intent. The author is concerned that the FDA may not be receiving enough information about adverse drug reactions to make informed decisions to protect the public health.

2) Enforcement. This bill lacks language that would make the bill enforceable. There is no way to know how many adverse drug reactions a health professional observes each year. Consequently this bill would be impossible to enforce. Additionally, it is unclear how each regulatory board would know that an event should have been reported, but wasn't.

3) FDA, MedWatch Program. MedWatch is a voluntary reporting program run by the FDA that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. Reporting is done on line, by phone, or by submitting the MedWatch 3500 form by mail or fax. The FDA disseminates medical product safety alerts, recalls, withdrawals, and important labeling changes to the medical community and the general public via its web site and the Med Watch E-list.

4) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a toll-free telephone number for the purpose of receiving reports of adverse drug reactions; 2) establish a Web site to provide up-to-date information to the public about adverse drug reactions; 3) maintain a database of adverse drug reaction reports; and 4) act as a liaison with appropriate parties to ensure the speedy and accurate flow of information about important drug safety issues.

AB 72 (Frommer) would require a manufacturer of prescription drugs that offers for sale, transfers, or furnishes a prescription drug in the state to submit a report of health studies to DHS that have been or are being conducted for each prescription drug it sells, transfers, or furnishes in the state. The measure would also give the Attorney General the authority to bring a civil action to enforce the requirements of bill.

5) History.

2005	
Mar. 14	Set for hearing March 30.
Feb. 24	To Com. on HEALTH.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 380

Introduced by Senator Alquist

February 17, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 380, as introduced, Alquist. Drugs: adverse event reporting.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would require a licensed health professional and a health facility to report serious adverse drug events that they observe to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch.

By changing the definition of a crime, this bill would impose a state–mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The federal Food and Drug Administration (FDA) operates a voluntary reporting system for adverse drug reactions known as the MedWatch system.

(b) The FDA currently estimates that only 10 percent of the adverse drug reactions or events that occur each year are reported to the FDA.

(c) Given the prevalence of pharmaceuticals and their use for treatment of hundreds of chronic diseases and conditions, and given recent highly publicized instances of commonly used prescription drugs being taken off the market due to safety concerns that were discovered after the drugs were approved for use, the systematic underreporting of adverse drug events represents a serious public health problem.

(d) Requiring licensed health professionals of organizations to report adverse drug events to the FDA would increase the amount of data available to the FDA about adverse drug reactions, thereby enabling the FDA to discern problems with drugs that arise after they are approved and to take action to protect the public health in a more timely manner.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Adverse Event Reporting

111657. (a) A licensed health professional, including, but not limited to, a physician and surgeon, dentist, or pharmacist, and a health facility, including, but not limited to, a hospital or clinic, shall report serious adverse drug events that they observe to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration.

(b) For purposes of this section, serious adverse drug events shall include adverse health outcomes involving patients that result in death, life–threatening conditions, hospitalization,

disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

(c) Any health professional or health facility that is required to report an adverse drug event pursuant to this section shall do so using the FDA 3500 Voluntary form developed by the federal Food and Drug Administration for MedWatch.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 401 **VERSION: INTRODUCED**

AUTHOR: ORTIZ **SPONSOR: ORTIZ**

RECOMMENDED POSITION:

SUBJECT: MEDICAL INFORMATION: PHARMACIES: MARKETING

Existing Law:

1) Defines marketing as "communication about a product or service that encourages recipients of the communication to purchase or use the product or service."

2) Excludes the following from the definition of marketing:

a. Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration from a third party for making the communication.

b. Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe

c. Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment for a chronic and seriously debilitating or life-threatening condition, if the health care provider, contractor, or health plan receives direct or indirect remuneration from a third party for making the communication, if all of the following apply:

i. The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

ii. The individual is provided the opportunity to opt out of receiving future remunerated communications.

iii. The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications.

(Civil Code 56.05)

This Bill:

Defines "marketing" to include a written communication that is provided to a pharmacy patient during a face-to-face interaction with a pharmacist or with pharmacy personnel, in conjunction with the dispensing of a prescription drug if:

1) the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs; and
2) the communication describes:
   a. biochemical, pharmacological, or other scientific or health information related to a disease or health condition for which the dispensed drug is indicated,
   b. a treatment or therapy for that disease or health condition, or
   c. the known after effects or consequences of that disease or condition.

(Civil Code 56.05 Amended)

Comment:

1) Author's Intent. The author's intent is to close a loophole that she sees in the law that allows drug manufacturers to distribute biased written information to patients through pharmacists during face-to-face drug consultations. An example would be an pharmacist giving a patient an advertisement, during the face to face consultation, that list other possible drugs that could be taken for the same condition. The author's intent is not to target advertising in patient information leaflets. Consequently, the author is likely to amend the bill to exclude advertising in leaflets from the provisions of the measure.

2) Background. AB 715 (Chan, Chapter 562, Statutes of 2003), sought to prohibit marketing practices where a health care provider or entity was paid to market a third party's product or service to a patient, using that patient's medical information. While the bill protected consumer privacy, it did not completely deal with issues surrounding third party marketing to consumers. The question arises, does permitting drug companies to pay for advertising or the production of fact sheets used by pharmacists in consultations with patients benefit or harm the consumer?

AB 746 (Mathews, 2003) was proposed as "clean-up" legislation to AB 715. AB 746 would have clarified that pharmacists had the right to provide patient pamphlets with drug manufacture advertising or messages that informed patients of about the drug they were receiving. Pharmacists argued that including advertisements helped pay for the costs of producing the pamphlets and that prohibiting advertising would result in patients receiving less information about the drug they are taking. AB 746 died in the Senate.

Likewise, SB 401 is also being proposed as "clean-up" legislation to AB 715, but unlike AB 746, it takes the position that marketing information from drug manufacturers during face-to-face interaction is bad for the consumer and should therefore be prohibited. Supporters of the measure argue that information from pharmacists should be free from bias and information from drug manufacturers may confuse patients and contradict the information they receive from their doctor.

4) Previous Legislation.

AB 715 (Chan, Chapter 562, Statutes of 2003) Personal Information.

AB 746 (2003) Medical Information: Pharmacies, Marketing; this measure died in the Senate.

5) History.

2005	
Mar. 16	Set for hearing April 6.
Feb. 24	To Coms. on HEALTH and JUD.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 401

Introduced by Senator Ortiz

February 17, 2005

An act to amend Section 56.05 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 401, as introduced, Ortiz. Medical information: pharmacies: marketing.

Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor. Existing law provides that this prohibition also applies to the marketing of medical information, as defined, excluding from that definition, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.

This bill would further provide that marketing includes a written communication that is provided by a pharmacy to a patient that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs, as specified. Because a violation thereof may be punishable as a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that the Legislature finds there is no mandate contained in the bill that will result in costs incurred by a local agency or school district for a new program or higher level of service which require reimbursement pursuant to these constitutional and statutory provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 56.05 of the Civil Code is amended to read:

56.05. For purposes of this part:

(a) "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information.

(b) "Authorized recipient" means any person who is authorized to receive medical information pursuant to Section 56.10 or 56.20.

(c) "Contractor" means any person or entity that is a medical group, independent practice association, pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care. "Contractor" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code or pharmaceutical benefits managers licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(d) "Health care service plan" means any entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(e) "Licensed health care professional" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or

Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(f) *(1)* "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

~~"Marketing"~~

(2) "Marketing" does not include any of the following:

~~(1)~~

(A) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.

~~(2)~~

(B) Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.

~~(3)~~

(C) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, as provided in Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, if all of the following apply:

~~(A)~~

(i) The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

~~(B)~~

(ii) The individual is provided the opportunity to opt out of receiving future remunerated communications.

~~(C)~~

(iii) The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free *telephone* number of the health care provider, contractor, or health plan making the remunerated communications. No further communication may be made to an individual who has opted out after 30 calendar days from the date the individual makes the opt out request.

(3) "Marketing" includes a written communication that is provided to a pharmacy patient during a face-to-face interaction with a pharmacist or with pharmacy personnel, in conjunction with the dispensing of a prescription drug, that describes biochemical, pharmacological, or other scientific or health information related to a disease or health condition for which the dispensed drug is indicated, a treatment or therapy for that disease or health condition, or the known after effects or consequences of that disease or condition, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.

(g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

(h) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.

(i) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. "Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.

(j) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 592 **VERSION: INTRODUCED**

AUTHOR: AANESTEAD **SPONSOR: CALIFORNIA SOCIETY OF HEALTH SYSTEMS PHARMACISTS**

RECOMMENDED POSITION:

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. Counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in pharmacy technology.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.

(CCR 1793.5, 1793.6)

This Bill:

1) Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose distribution systems. (B&P 4128 Added)

2) Requires hospitals implementing TCT to meet the following requirements:

a. Conduct training for technicians that is the same training pharmacists receive do the same work.

b. Conduct a continuous quality improvement program.

c. Possess a current accreditation from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) or other nationally recognized accrediting organization.

d. Establish a program using pharmacists to provide clinical services.

(B&P 4128 Added)

Comment:

1) Author's Intent. The author is seeking to apply the model TCT program evaluated in a study project at Cedars Sinai Medical Center and Long Beach Memorial Hospital. The results of that study were published in the American Journal of Health System Pharmacy, June 2002, (attached) and found the practice to be safe and that TCT allowed staff pharmacists to spend more time addressing clinical issues with patients and prescribers.

2) Legislative History. In 2003 the author introduced SB 393, a bill similar to SB 592. SB 393 was opposed by the United Food and Commercial Union (labor), consequently the measure failed to make it beyond its second committee hearing.

The sponsor of SB 592 is engaging labor in discussions in hopes labor will either support or remain neutral on the bill.

2) Board History. At its October 2001 meeting, the board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician filling unit-dose cassettes in an inpatient hospital pharmacy. At that meeting the board expressed a desire for TCT programs to emulate those operated by Cedars-Sinai and Long Beach Memorial under the board waiver.

In April 2003, the board voted to support SB 393.

At the January 2004 board meeting the board approved a two-year pilot program at UCSF / Cedars to allow TCT to continue while documentation of duties preformed by pharmacists continue. This pilot program will end in 2006.

5) History.

2005	
Mar. 3	To Com. on B., P. & E.D.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 592

Introduced by Senator Aanestad

February 18, 2005

An act to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy technicians.

LEGISLATIVE COUNSEL'S DIGEST

SB 592, as introduced, Aanestad. Acute care hospitals: inpatient pharmacy technician services.

Existing law, the Pharmacy Law, provides for the regulation of the practice of pharmacy by the California State Board of Pharmacy, in the Department of Consumer Affairs. Existing law authorizes a registered pharmacy technician to assist in the performance of pharmacy related duties under the supervision of a licensed pharmacist. A violation of the Pharmacy Law is a crime.

This bill would authorize a general acute care hospital to implement a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for certain patients, if specified requirements are met.

Because a failure to meet the training requirements in this bill would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. Inpatient Pharmacy Technician Services

4128. Notwithstanding any other provision of this chapter or any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. A hospital implementing and operating a program pursuant to this section shall meet all of the following requirements:

(a) The hospital shall conduct a special training program for technicians who perform the checking function that provides the technicians with the same training that a pharmacist would be provided with under paragraph (1) of subdivision (b) of Section 4052.

(b) The hospital shall conduct a continuous quality improvement program.

(c) The hospital shall establish and maintain a program utilizing pharmacists to provide clinical services, as described in Section 4052.

(d) The hospital shall have a current, nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a

crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 644 **VERSION: INTRODUCED**

AUTHOR: ORTIZ **SPONSOR: PLANNED PARENTHOOD**

RECOMMENDED POSITION:

SUBJECT: DISPENSING OF PRESCRIPTIONS

Existing Law:

1) Permits pharmacists to dispense emergency contraception (EC) without a prescription if a protocol is established with a prescriber or the protocol established by the board. (B&P 4052)

2) Establishes procedures for dispensing EC without a prescription. (CCR 1746)

3) Requires a pharmacist who declines to distribute EC to refer the patient to another EC provider. (CCR 1746)

This Bill:

Requires a pharmacist to dispense a "lawful" prescription unless one of the following circumstances exists:

1) Dispensing the prescription is contrary to law or is contraindicated for the patient.

2) The pharmacy does not have the dangerous drug that was prescribed in its stock. The pharmacist shall immediately notify the patient and promptly transfer the prescription to another pharmacy known to stock the dangerous drug or, upon the patient's request, return the prescription to the patient and refer the patient to a pharmacy known to stock the dangerous drug.

3) The pharmacist refuses on ethical, moral, or religious grounds to dispense a dangerous drug pursuant to an order or prescription. A pharmacist may decline to dispense a dangerous drug on this basis only after:

a. Notifying his or her employer, in writing, of the drug or class of drugs to which he or she objects; and

b. The pharmacist's employer can, without creating undue hardship, including undue hardship to the patient, provide a reasonable accommodation of the pharmacist's objection by establishing protocols that ensure that the patient has timely access to the prescribed dangerous drug despite the pharmacist's refusal to dispense the prescription.

(B&P 4050.1 Added)

Comment:

1) Author's Intent. The author and sponsor are concerned that even with current laws in place, pharmacist are refusing to dispense EC to patients. SB 644 clarifies in law that pharmacists are not permitted to abandon their patients.

2) Consistency. SB 644 is consistent with current EC regulations that allow a pharmacist to opt-out of filling a prescription, based on moral, ethical or religious grounds, if a patient can be referred to another pharmacist to fill a prescription.

3) Enforcement. Enforcement of SB 644 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacists' refusal to dispense EC. Consequently, if SB 644 were enacted, the board does not anticipate a huge increase in consumer complaints regarding refusal to fill prescriptions.

4) Necessity for Law? Pharmacy law and regulation (B&P 4052 & CCR 1746) require a pharmacist to fill EC prescriptions, or refer a patient to another pharmacist or pharmacy when a pharmacist is unable to fill a prescription for EC. The board has not encountered any problems with enforcing this law. Consequently, it would seem as though SB 644 duplicative of current law.

5) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation. SB 545 (Chapter 652, Statutes of 2003) clarified many of the provisions in SB 1169. The board took a neutral position on the bill.

6) Related Legislation. AB 21 (Levine 2005) Pharmacist: Contraceptive Devices, would prohibit a pharmacist from declining to dispense a contraceptive or emergency contraceptive. AB 21 does not contain an op-out clause for pharmacist who chooses not to fill EC prescriptions, nor does the measure require a pharmacy to establish protocols in the event that a pharmacist or pharmacy is unable to fill a prescription for EC.

7) History.

2005	
Mar. 17	Set for hearing April 11.
Mar. 3	To Coms. on B., P. & E.D. and HEALTH
Feb. 24	From print. May be acted upon on or after March 26.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 644

Introduced by Senator Ortiz

February 22, 2005

An act to add Section 4050.1 to the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

SB 644, as introduced, Ortiz. Dispensing of prescriptions.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of those provisions a crime. Existing law prohibits, except as specified, a person other than a pharmacist from dispensing a dangerous drug, as defined, pursuant to a prescription.

This bill would require a pharmacist to dispense a lawful prescription except in specified circumstances, including on ethical, moral, or religious grounds asserted by the pharmacist. The bill would authorize the pharmacist to decline to dispense the prescription on that basis only if his or her employer is able to reasonably accommodate that objection.

Because violation of the bill would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares the following:

(a) Patients should have timely access to medications that are lawfully prescribed for them.

(b) When engaging in the practice of pharmacy, a pharmacist must exercise professional judgment in the best interest of a patient's health and respect a patient's dignity and autonomy and maintain the confidentiality of a patient's medical information.

SEC. 2. Section 4050.1 is added to the Business and Professions Code, to read:

4050.1. Notwithstanding any other provision of law, a pharmacist shall dispense a lawful prescription unless one of the following circumstances exists:

(a) Based on the pharmacist's professional training and judgment, dispensing the prescription is contrary to law or is contraindicated for the patient.

(b) The pharmacy does not have the dangerous drug that was prescribed in its stock. The pharmacist shall immediately notify the patient and promptly transfer the prescription to another pharmacy known to stock the dangerous drug or, upon the patient's request, return the prescription to the patient and refer the patient to a pharmacy known to stock the dangerous drug.

(c) The pharmacist refuses on ethical, moral, or religious grounds to dispense a dangerous drug pursuant to an order or prescription. A pharmacist may decline to dispense a dangerous drug on this basis only after notifying his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the pharmacist's employer can, without creating undue hardship, including undue hardship to the patient, provide a reasonable accommodation of the pharmacist's objection by establishing protocols that ensure that the patient has timely access to the prescribed dangerous drug despite the pharmacist's refusal to dispense the prescription. For purposes of this subdivision, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (j) of Section 12940 of the Government Code, and "dangerous drug" includes the drug therapy described in paragraph (8) of subdivision (a) of Section 4052.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 734 **VERSION: INTRODUCED**

AUTHOR: TORLAKSON **SPONSOR: DEPARTMENT OF JUSTICE**

RECOMMENDED POSITION:

SUBJECT: CONTROLLED SUBSTANCES

Existing Law:

1. Provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements. (H&S 11159.2)

2. Provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order. (H&S 11161)

3. Provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the board; the board may approve security printer applications after the board has completed a state and federal criminal background check. (H&S 11161.5)

4. Provides that the board or the Department of Justice (DOJ) may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime. (H&S 11161.5)

5. Provides that prescription forms shall be printed with specified features. (H&S 11162.1)

6. Provides that with respect to specified controlled substances each dispensing pharmacy or presciber shall provide specified information to the Department of Justice, as specified. (H&S 11190)

This Bill:

This bill would make several changes to facilitate the operation of Controlled Substances Utilization Review and Utilization Review and Evaluation System (CURES) and to allow for consistency with existing DOJ policy and practice and conformity with "best practices" model to prevent diversion of controlled substances. The bill would make the following changes:

1. Transfers responsibility from the board to DOJ to control the manner in which fingerprints are provided when conducting criminal background investigations of vendors applying to print security prescription forms.

   a. Allows DOJ to collect fees

   b. Extends from 30 days to 60 days the period with which DOJ may deny an application.

c. Allows DOJ to retain fingerprint impressions for subsequent enforcement and arrest.

d. Allows DOJ and the board to examine the books of security printers.

(H&S 11161.5 Amended)

2 Allows the terminally ill exemption (allowing a prescriber to use nonsecurity forms) for any controlled substance prescription. (Current law designates only C II drugs can be prescribed in this manner.) (H&S 11159.2 Amended)

3. Authorizes the Superior Court to order a prescriber not to order, obtain, or use any prescription forms during a pending criminal action. (H&S 11161 Amended)

4. Clarifies that DOJ is solely responsible for determining whether security printer applications are complete, for maintaining a list of approved security printers, and for revoking approval of security printers. (H&S 11161.5 Amended)

5. Clarifies how prescribers and physician assistants can state number of prescriptions included on form and otherwise comply with CURES program. (H&S 11162.1 Amended)

6. Requires prescribers to pre-print their specific schedule II prescribing privileges and to a check a box by the name of the prescriber writing the prescription. (H&S 11161 Amended)

7. Requires approved security printers to print forms with a vendor identification code issued by the DOJ. (H&S 11162.1 Amended)

8 Requires pharmacists to indicate method of payment from patients for each schedule II or III controlled substance purchased into CURES. Also prescribers who dispense C II and CIII must report this as well too. (H&S 11165 Amended)

9 Requires direct dispensers of controlled substances to submit information to the DOJ in a format specified by the DOJ. (H&S 11190 Amended)

10. Makes other technical changes to allow for consistency with existing DOJ policy and practice.

Comment:

1) Author's Intent. The bill is sponsored the DOJ. The author's intent is to make technical and clean-up changes to facilitate the effective operation of the CURES and the program duties of the Bureau of Narcotics Enforcement. Additionally, this bill would make technical changes to be consistent with existing DOJ policy and practice and conform to their "best practices" model to prevent diversion of controlled substances.

2) Above and Beyond Current Requirements: Provisions in AB 734 go beyond transferring oversight of the security printer program from the board to DOJ. New provisions would:

a. Expand DOJ authority to:

   i. Retain the figure prints of applicants.

   ii. Extend the time to review security printer applications from 30 to 60 days.

   iii. Deny an application for a security printer if an applicant is found to have been convicted of a crime or if the applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime.

iv. Inspect a security printer's business, or examine books and records anytime during regular business hours.

b. Expand information required on prescription forms to include:

i. Checkboxes for schedule II-V for prescriber's authority.

ii. Identification number of security printer.

c. Require pharmacies to inform DOJ by inputting into CURESof the method of payment used by patients to purchase schedule II and III drugs.

This bill expands and alters the components required on a security form. It expands the information pharmacies must submit to CURES.

The board submitted a modification to section 11165 to cap the board's funding to CURES at the amount approved by the Governor and the Legislature. This amendment needs to be included in the bill. (See attached.)

Many of these requirements seem excessive. Specifically, the requirement that prescription forms list the schedule of drugs a prescriber can prescribe. There is no means for a pharmacist to check if a prescriber is prescribing out of class. Additionally, what happens if a prescriber's authority changes? Would the prescriber be obligated to use new forms with updated prescribing authority? There does not appear to be a benefit from having this information on prescription forms.

3) Previous Legislation. SB 151 (Burton, 2003, Chapter 406) implementing the "Pain Treatment and Diversion Act of 2003," the Controlled Substances Utilization Review and Evaluation System (CURES) became permanent.

4) History.

2005	
Mar. 16	Set for hearing April 6.
Mar. 10	To Coms. on HEALTH and PUB. S.
Feb. 23	From print. May be acted upon on or after March 25.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 734

Introduced by Senator Torlakson

February 22, 2005

An act to amend Sections 11159.2, 11161, 11161.5, 11162.1, 11165, and 11190 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 734, as introduced, Torlakson. Controlled substances.

(1) Existing law provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements.

This bill would impose these requirements on any prescription for a controlled substance for use by a patient who has a terminal illness.

(2) Existing law provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order.

This bill would require the court, in its order, to also prohibit the practitioner from obtaining, ordering, or using any additional prescription forms. The bill would impose a state-mandated local program by requiring the law enforcement agency obtaining the order to notify the Department of Justice of the order. The bill would make clarifying and conforming changes to this and related provisions.

(3) Existing law provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy; the board may approve security printer applications after the applicant has provided specified information and the applicant's fingerprints, in a manner specified by

the board, for the purpose of completing state and federal criminal background checks.

This bill would revise the latter provision to provide instead that the prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice and that the department shall provide the applicant with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks. The bill would provide that the applicant shall submit his or her fingerprint images and related information to the department for the purpose of the department obtaining information as to the existence and nature of a record of specified state, federal, or foreign level convictions and arrests. Requests for federal level criminal offender record information received by the department shall be forwarded to the Federal Bureau of Investigation by the department. The bill would provide that the department shall assess the applicant a fee sufficient to cover all processing or maintenance costs of the department associated with providing the background checks, as specified.

(4) Existing law provides that the Board of Pharmacy or the Department of Justice may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime.

This bill would provide that the Department of Justice, but not the Board of Pharmacy, may deny the security printer application for the specified reasons, including if any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant who has direct access, management, or control of controlled substance prescription forms has been convicted of a crime. The bill would also add as a condition for approval as a security printer that the applicant authorize the board or department to make any examination of books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce the provisions relating to security printers.

(5) Existing law provides that prescription forms shall be printed with specified features.

This bill would provide that prescription forms shall also include the feature of an identifying number assigned to the approved security printer by the Department of Justice. The bill would also require the

forms to set forth specified information, as appropriate, with respect to practitioners with privileges to prescribe scheduled controlled substances, physician assistants authorized to issue a drug order, and multiple prescribers.

(6) Existing law provides that with respect to specified controlled substances each dispensing pharmacy or presciber shall provide specified information to the Department of Justice, as specified.

This bill would require the information from the dispensing pharmacy to include the method of payment for the prescription and the information from the dispensing prescriber to be provided to the department in a format set by the department.

(7) Existing law generally provides that a violation of the provisions relating to the prescription of controlled substances is a misdemeanor, punishable as specified. This bill, to the extent it revises existing crimes, would impose a state-mandated local program upon local governments.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11159.2 of the Health and Safety Code is amended to read:

11159.2. (a) Notwithstanding any other provision of law, a prescription for a ~~Schedule II~~ controlled substance for use by a patient who has a terminal illness shall meet the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(d) This section shall become operative on July 1, 2004.

SEC. 2. Section 11161 of the Health and Safety Code is amended to read:

11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all ~~triplicate prescription blanks or~~ controlled substance prescription forms in the practitioner's possession at a time set in the order *and which prohibits the practitioner from obtaining, ordering, or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order.* Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the

court. Any practitioner possessing prescription ~~blanks~~ *forms* in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender ~~all triplicate prescription blanks or~~ *controlled substance prescription forms and to prohibit the defendant from obtaining, ordering, or using* controlled substance prescription forms, with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on November 1, 2004.

SEC. 3. Section 11161.5 of the Health and Safety Code is amended to read:

11161.5. (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the ~~Board of Pharmacy~~ *Department of Justice.*

(b) The ~~Board of Pharmacy~~ *department* may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; and all managing general partners, if any.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, or managing general partner.

(5) (A) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The ~~applicant~~ *department* shall ~~also~~ provide *the applicant with the means and direction to provide* fingerprints *and related information*, in a manner specified by the ~~Board of Pharmacy~~ *department*, for the purpose of completing state ~~and~~, federal, *or foreign* criminal background checks.

(C) *Any applicant described in subdivision (b) shall submit* his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the *department establishes that the* applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision *(l)* of Section 11105 of

the Penal Code. Requests for federal level criminal offender record information *received by the department* pursuant to this section shall be forwarded to the Federal Bureau of Investigation *by the department.*

(D) The department shall assess against each applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits fingerprints and related information to the department.

(E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

(c) ~~Prior to approving a security printer application, the Board of Pharmacy shall submit a copy of the application to the Department of Justice; the Department of Justice may, within 30~~ *The department may, within 60* calendar days of receipt of the application from the ~~Board of Pharmacy~~ *applicant*, deny the security printer application.

(d) The ~~Board of Pharmacy or the Department of Justice~~ *department* may deny a security printer application on any of the following grounds:

(1) The applicant, *any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms,* has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The ~~Board of Pharmacy or Department of Justice~~ *department* determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The ~~Board of Pharmacy or Department of Justice~~ *department* determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Board of Pharmacy or Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) The ~~Board of Pharmacy~~ *department* shall maintain a list of approved security printers and the ~~Board of Pharmacy~~ *department* shall make this information available to prescribers and other appropriate government agencies, including the ~~Department of Justice~~ *Board of Pharmacy*.

(f) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances.

(g) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer.

(h) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(i) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(j) (1) The ~~Board of Pharmacy or the Department of Justice~~ *department* may revoke its approval of a security printer for a

violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the ~~Board of Pharmacy or the Department of Justice~~ *department* revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

~~(k) Security printer applicants may appeal a denial or revocation by the Board of Pharmacy to the full board in a public meeting of the Board of Pharmacy.~~

SEC. 4. Section 11162.1 of the Health and Safety Code is amended to read:

11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermo-chromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form and the following quantities shall appear:

1-24
25-49
50-74
75-100
101-150
151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall ~~either (A)~~ contain a statement printed on the bottom of the prescription blank that the

~~"Prescription is void if more than one controlled substance prescription is written per blank" or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the~~ "Prescription is void if the number of drugs prescribed is not noted."

(9) *(A)* The preprinted name, category of licensure, license number, ~~and~~ federal controlled substance registration number of the prescribing practitioner.

(B) The privileges of a practitioner to prescribe any of the following controlled substances shall be preprinted beside the prescriber's name and as designated in the prescriber's certificate issued by the federal Drug and Enforcement Agency:

(i) Schedule II narcotic.

(ii) Schedule II nonnarcotic.

(iii) Schedule III narcotic.

(iv) Schedule III nonnarcotic.

(v) Schedule IV.

(vi) Schedule V.

(10) A check box indicating the prescriber's order not to substitute.

(11) An identifying number assigned to the approved security printer by the Department of Justice.

(12) A physician assistant authorized by Section 3502.1 of the Business and Professions Code to issue a drug order may do so under his or her own name on prescription forms preprinted with the information required by Section 11162 that are in compliance with subdivision (d) of Section 3502.1 of the Business and Professions Code.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated

prescriber and the name, address, category of licensure, and license number of the licensed health care facility preprinted on the form.

(3) *(A) Forms ordered pursuant to this subdivision that list multiple prescribers on one prescription form shall have a check box by the name of each designated prescriber.*

(B) Each designated prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by the prescriber's name.

(4) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

~~(4)~~

(5) (A) The designated prescriber shall maintain a record of the prescribers to whom controlled substance prescription forms are issued.

(B) The record shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber; the record shall be maintained in the health facility for three years.

(d) This section shall become operative on July 1, 2004.

SEC. 5. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II and Schedule III controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and format specified by the Department of Justice:

(1) Full name, address, gender, and date of birth of the patient.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.
(6) ICD-9 (diagnosis code), if available.
(7) Date of issue of the prescription.
(8) Date of dispensing of the prescription.
(9) Method of payment for prescription.
(e) This section shall become operative on January 1, 2005.

SEC. 6. Section 11190 of the Health and Safety Code is amended to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:
(1) The name and address of the patient.
(2) The date.
(3) The character, including the name and strength, and quantity of controlled substances involved.
(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.
(c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:
(A) Full name, address, gender, and date of birth of the patient.
(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(C) NDC (National Drug Code) number of the controlled substance dispensed.
(D) Quantity of the controlled substance dispensed.
(E) ICD-9 (diagnosis code), if available.
(F) Date of dispensing of the prescription.
(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in ~~either hardcopy or electronic form~~ *a format set by the Department of Justice.*
(d) This section shall become operative on January 1, 2005.

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

However, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

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State of California Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee Date: March 25, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Initiative Update

In January 2005, the Secretary of State requested the board analyze three proposed initiatives relating to prescription drugs. The proposed initiatives and the board's draft analysis of the initiatives are attached.

SA05RF0051 - Prescription Drugs. Initiative Statute.
Status: In circulation

SA05RF0052 - Prescription Drugs Act. Initiative Statute.
Status: In circulation

SA05RF0065 - California State Pharmacy Assistance Program (CAL Rx)
Status: Attorney General awaiting preparation of title and summary

SA2005RF0051

1. The greatest concern of the board is posed by Section 22999 of the Act.

   Section 22999 directs that the Act be "broadly construed and applied" and would supercede any other existing law that is in conflict with the Act's protections, making such existing law "null an void" and "hereby repealed." However, any number of pharmacy laws that could be in conflict and yet remain on the books, making identification of current requirements difficult if not impossible (affecting compliance by licensees as well as enforcement by the board).

   Moreover, the provisions in the Act could not be amended except by a 2/3 vote of both houses or by another voter-approved initiative. Any subsequent amendments to the Act must "further" the purpose of the Act. Any provision declared invalid by a court would be severed from the rest of the Act's provisions. Any conflicts with other ballot initiatives would be superceded by provisions in this Act, and if the initiative receives more votes than other initiatives on the ballot, the other initiatives would be "null and void."

   It is usually necessary to pursue cleanup provisions after enactment of any new regulatory program. The provisions above would make such amendments very difficult, and potentially open to challenge. This would prevent the board from correcting flaws in the enacting provisions and could make implementation and regulation of the program impossible.

2. The board is charged to enforce provisions of Section 5 of the initiative, titled as Article 25. As such, we will not generally comment on the other provisions charged to PERS for enforcement.

3. The Board of Pharmacy (BOP) would not be provided with any funding for startup costs for the program. The provision of $5 million in startup costs is allocated only to the Board of Administration of PERS (section 22988).

4. Likely revenue from this program could be substantial. There are 450 manufacturers in California licensed with the Department of Health Services. This does not include the many manufacturers located outside California who ship drugs into this state and would be subject to the initiative's provisions. If all these manufacturers registered, this would be $11,250,000 annually. It is difficult to determine how many "drug marketers" would become licensed in California. There are more than 100,000 physicians, and thousands of other practitioners who are authorized to prescribe within their scope of practice (dentists, podiatrists, optometrists, nurse practitioners, pharmacists, physician assistants). Say there are only 5,000 detail persons who market to these practitioners, this would generate $3,750,000 more annually. A total revenue, before any fines are deposited, of $15,000,000.

5. Under section 4450:
   (a) The BOP has six months from voter approval to implement the licensing provisions of this act. This is a very short period of time to set up a licensure program to issue licenses, and be positioned to process and issue annual renewals. However, the bill does not contain parameters for licensure, so any drug marketer or manufacturer employing marketers submitting an application would have to be licensed. There is no criteria to deny an applicant a license (there are no qualifications), so submitting an application would result in issuance of a license. The result is more a registry of those doing business in California than a licensure program.

   The BOP must implement the program without additional staff and without funding for startup costs. If only 450 manufacturers and 5,000 drug marketers apply for registration, absorbing this workload without staff and resources within only six months would be difficult, even if there are virtually no components for qualifying for the license. Setting up such a program so quickly would cause redirection of staff from most other board functions, impacting all board operations. The six-month set up provisions would make it difficult to hire and train additional staff even if (in the unlikely event) that existing funding could be identified by the board to redirect to this function.

   (b) The BOP would enforce only the following provisions against marketers or manufacturers (since determining excessive prices and unjust or unreasonable profits charged by manufacturers would be enforced by PERS):
      1. Licensees will not engage in unfair or deceptive acts or practices
      2. Marketers will disclose to prescribers health risks of and clinical trial results of EACH prescription drug directly marketed to the prescriber.
      3. Manufacturers must post on their Web sites the health risks and clinical trail of ALL drugs marketed.

   The Article provides no guidance as to what unfair or deceptive acts are, other than those listed in item 2 (failure to disclose information to a practitioner about a specific drug promoted) and item 3 (not posting all information on a manufacturer's Web site). Should the BOP attempt to take enforcement action outside of items 2 and 3, it would have no authority, and would likely be sued. The BOP similarly would lack the authority to pursue regulations to define "unfair or deceptive acts or practices" because the Article is so limited in its description of the BOP's duties.

6. Under section 4451: violation of any provision in the Article is grounds for revocation or suspension by the BOP; however, there would be no grounds to deny the application of a revoked licensee for a new license the next day, unless regulations to this effect are promulgated.

7. Under section 4552: the BOP shall require that "each licensee that is not a pharmaceutical drug manufacturer" who markets drugs in CA must pay a licensure fee of $750. However, there is no application fee to convert a marketer applicant to a licensee. Similarly, the BOP shall require each drug manufacturer who employs or contracts for marketers a fee of $25,000 annually. If a manufacturer does not use a "marketer" in California, then no licensure fee is presumably required. Again, there is no application fee to convert a manufacturer applicant to a licensee.

8. Under section 4453: the BOP is authorized to fine individuals ($5,000) and manufacturers ($25,000) who violate provisions of the Article; this would be limited to unlicensed activity, performing detailing or having a marketer detail without the manufacturer's being licensed, having drug information missing from a manufacturer's Web site, or performing duties with a revoked or suspended license. Each act of promotional activity is a separate violation. But the AG, DA, county council, city attorney or prosecutor can also bring a civil action to enforce provisions of the Article. Thus, even if the BOP does not act for unlicensed activity, a state or local prosecutor could. While multiple agencies could be involved in prosecuting the same violation by a manufacturer, this is unlikely because under provisions of 4454, all fines are to be deposited into the "Prescription Drug Discount Fund" regardless of who collects the fine. Also, enforcement of this Act is further convoluted because violations of other provisions of the Act determined and enforced by PERS would not be violations of this Article.

9. Under section 4454: licensure fees deposited by board in the Prescription Drug Discount Fund will pay costs associated with Act. The BOP is capped to spend no more than $2 million annually to the licensing and specified oversight of marketers and manufacturers. Additional appropriations can be authorized by a majority vote of the Legislature (not the 2/3 vote required for budget appropriations in the Legislature). If $15 million or more is collected annually, there could be a sizeable reserve in this fund in several years' time.

10. Under section 4455: the BOP must adopt rules required for this Article. Unless adopted as emergency regulations, it takes typically nine months or longer to adopt and implement regulations. The BOP is not certain what regulations would be needed to enforce provisions of the Article.

11. Under section 4456: the Article contains definitions. The definition of manufacturer is overly broad and would include under the provisions "any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of drug products," pharmacies and wholesalers (even though the provisions exclude a licensed pharmacist). Pharmacies and wholesalers, who are already licensed by the board, routinely perform some of these functions and would be subject to the additional annual licensure fee of $25,000. This would have a chilling effect on pharmacies, wholesalers, and drug distribution generally in California. Moreover, the board issues individual licenses to each wholesaler or pharmacy site operating in California. The Act is unclear whether a single owner needs a license or each site must be

separately licensed; thus Rite Aid, which has about 600 pharmacies in California, which packages and distributes drug products from each of these sites, could need 600 licenses or merely one.

SA2005RF0065

This initiative does not really impact the jurisdiction of the Board of Pharmacy.

Our only comment is to note that under section 130601(i), the program would limit its provisions only to dangerous drugs thereby excluding dangerous devices (which are prescription-required items typically used to administer drugs or items that frequently are called durable medical equipment).

SA2005RF0050

SECTION 1. Title.

This Act shall be known as the "Affordable and Safe Prescription Drugs for All Californians Act"

SECTION 2. Findings and Declarations.

The People of California find and declare the following:

Prescription drugs cost 70% more in California than they do in other countries. Drug companies knowingly sell dangerous drugs.

Other countries use their buying power to negotiate prescription drug discounts. The State of California negotiates drug discounts on behalf of state workers, elected officials and the Governor. Existing laws do not allow most Californians to access similar discounts.

Therefore, the People of California declare that reform is necessary. First, all Californians shall be allowed to join a discount program to access affordable prescription drugs at local pharmacies. Second, this program will operate on a key market principle: the bigger the buyer, the better the price. Third, drug companies and marketers will be required to tell doctors and the public about the health risks of prescription drugs. Drug companies and marketers shall pay a fee to cover the costs of administering these new laws so that this reform will cost taxpayers nothing.

SECTION 3. Purpose and Intent.

The purpose of this Act is to provide all Californians access to affordable and safe prescription drugs.

SECTION 4. Part 9 (commencing with Section 22980) is added to Division 5 of Title 2 of the Government Code, to read:

22980. This chapter shall be known and be cited as the Affordable and Safe Prescription Drugs for All Californians Act ("Act")

Article 1. Voluntary Access to Prescription Drug Discounts

22981. Any individual, regardless of income or insurance status, shall be allowed to join a prescription drug discount program administered by the Board of Administration of the Public Employees' Retirement System ("Board").

22982. The Board shall issue a pharmacy card to each new enrollee to access prescription drug discounts at the same pharmacies and pharmacy networks available to state workers. The Board shall provide enrollees access to a mail-order pharmacy option.

22983. The Board shall establish procedures for continuous open enrollment to the discount program. Enrollment forms shall be made available on the Board's Web site, at participating pharmacies, physician offices and at various other locations deemed appropriate by the Board.

22984. The Board may require an enrollee to pay an annual fee that proportionally reflects the administrative cost of providing prescription drug discounts to the enrollee, except that no enrollee fee shall be required if licensing fees and fines collected under Article 25 of Chapter 9 of Division 2 of the Business and Professions Code provide for the full cost of the program. The annual enrollee fee shall not exceed ten dollars ($10) per year adjusted annually to reflect the rate of inflation.

22985. The Board may enter into contracts with entities offering services related to the administration of pharmacy benefits, or with an entity that negotiates price discounts, rebates or other savings on prescription drugs with prescription drug manufacturers, wholesalers, or pharmacies.

22986. (a) The Board shall inform the public about their eligibility under the Act through press releases, public services announcements, television, radio and newspaper advertisements, announcements on state websites and written materials, and other means. The Board shall coordinate outreach activities with the California Department of Aging and other state and local agencies.

(b) No outreach material shall contain the name or likeness of a prescription drug, pharmaceutical drug manufacturer, or elected official. The annual cost of these outreach activities shall not exceed $1 million. If deemed appropriate by the Board, additional outreach and advertising expenses may be approved by the legislature by a statute passed in each house by roll call vote entered in the journal, fifty percent plus one of the membership concurring. Annual outreach costs shall be paid out of the Prescription Drug Discount Fund.

22987. The Prescription Drug Discount Fund is hereby established and shall be maintained in the State Treasury to accept fees related to enrollment in the program and licensing fees and fines collected under Article 25 of Chapter 9 of Division 2 of the Business and Professions Code. Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the Board for purposes of the administration and maintenance of the pharmaceutical purchasing program.

22988. The Board may request from the state Legislature, and the Legislature shall provide, up to $5,000,000 to pay for initial startup costs associated with the implementation of this Act. Licensing fees and fines collected under Article 25 of Chapter 9 of Division 2 of the Business and Professions Code shall be used to repay monies provided to pay for initial startup costs.

22989. Enrollees shall pay the discounted price for prescription drugs negotiated by the Board at participating pharmacies. The amount to be paid for those drugs by enrollees may include a pharmacy dispensing fee of no more than three dollars and fifty cents per prescription adjusted annually to reflect the rate of inflation.

22990. Following public comment, the Board may adopt a preferred drug list. If the Board adopts a preferred drug list, the Board shall provide for periodic public review of, and consider suggested changes to, the preferred drug list.

22991. The Board may adopt all necessary rules and regulations to carry out the provisions of this Act. The Board shall have the authority reasonably necessary to carry out the powers and responsibilities expressly granted or imposed upon it under this Act.

SECTION 5. Safe Prescription Drugs

Article 25 (commencing with Section 4450) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

4450. (a) No person may act as a prescription drug marketer unless such person, and the pharmaceutical drug manufacturer represented by the person, has first secured a license from the Board of Pharmacy. The Board of Pharmacy shall implement this Article no later than six (6) months after voter approval of this measure.

(b) A person or manufacturer licensed under this section:

(1) Shall not engage in any unfair or deceptive acts or practices.

(2) Shall disclose to a physician or any other person licensed to prescribe prescription drugs in this state, the health risks of, and results of any clinical trials regarding the health risks of, each prescription drug directly marketed to the physician or other person authorized to prescribe prescription drugs.

(c) A manufacturer licensed under this section shall disclose on the manufacturer's website the health risks of, and the results of any clinical trials regarding the health risks of, each prescription drug marketed by a licensed marketer employed by or representing the manufacturer in this state.

4451. A person or pharmaceutical drug manufacturer who violates a provision of this Article may be subject to revocation or suspension of the license granted under this Article.

4452. (a) The Board of Pharmacy shall require each licensee that is not a pharmaceutical drug manufacturer to pay an annual fee of $750.00.

(b) The Board of Pharmacy shall require a manufacturer employing or contracting for a prescription drug marketer or marketers in this state to pay an annual fee of $25,000 per manufacturer.

4453. A person other than a pharmaceutical drug manufacturer who violates a provision of Article, including a person who engages in the activities of a prescription drug marketer after his or her license has been revoked or suspended, shall be fined $5,000 by the Board of Pharmacy. A manufacturer who violates a provision of this Article shall be fined $25,000 by the Board of Pharmacy. The Attorney General or a district attorney, county council, city attorney, or city

prosecutor may bring a civil action to enforce the provisions of this Article. Each unlawful act of prescription drug promotional or marketing activity shall constitute a separate violation of this Article.

4454. License fees and fines shall be deposited into the Prescription Drug Discount Fund, as defined under Section 22987 of the Government Code, to pay for costs associated with the Affordable and Safe Prescription Drugs for All Californians Act. No more than $2,000,000 of these fees and fines may be retained annually by the Board of Pharmacy to pay for necessary expenses related to the licensing and oversight of marketers and manufacturers. Additional funds to implement this section may be approved by the legislature by a statute passed in each house by a roll call vote entered in the journal, fifty percent plus one of the membership concurring.

4455. (a) The Board of Pharmacy may adopt all necessary rules and regulations to carry out the provisions of this Article. The Board of Pharmacy shall have the authority reasonably necessary to carry out the powers and responsibilities expressly granted or imposed upon it under this Article.

(b) In the event that the Board of Pharmacy ceases to exist, or its duties are subsumed by, or transferred to, another entity, the authorities and duties of this Article shall be transferred to the California Department of Health Services.

4456. For the purposes of this Article:

(a) "prescription drug marketer" or "marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician or any other person licensed to prescribe prescription drugs.

(b) "Pharmaceutical drug manufacturer" or "manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a licensed pharmacist.

(c) "prescription drug" means any of the following:
(1) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
(2) Any drug or device that, pursuant to federal or state law, may be dispensed only with a prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code.
(3) "prescription drug" does not include labeled veterinary drugs.

(d) "marketed" means any promotional or marketing activity carried out by the prescription drug marketer or pharmaceutical drug manufacturer.

(e) "Board of Pharmacy" means the California Board of Pharmacy.

(f) "clinical trial" means a systematic evidenced based research study designed to answer specific questions about new or existing prescription drugs, or new ways of using known treatments.

SECTION 6. Joint Purchasing

Section 22851 of the Government Code is amended to read:

The Board may enter into any joint purchasing arrangement with private or public entities if the arrangement does not jeopardize the system's tax status or its governmental plan status.

SECTION 7. Definitions and Technical Matters

Section 22998 and 22999 are added to Part 9 of Division 5 of Title 2 of the Government Code, to read:

22998. For the purposes of this part:
(a) "Enrollee" means any individual enrolled in the prescription drug discount program provided by the Affordable and Safe Prescription Drugs for All Californians Act.

(b) "Program" or "discount program" means the prescription drug discount program provided by the Affordable and Safe Prescription Drugs for All Californians Act.

(c) "Board" means the Board of Administration of the Public Employees' Retirement System.

(d) "pharmaceutical drug manufacturer" or "manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs. The term does not include a licensed pharmacist.

(e) "prescription drug" means any of the following:
(1) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
(2) Any drug or device that, pursuant to federal or state law, may be dispensed only with a prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code.
(3) "prescription drug" does not include labeled veterinary drugs.

22999. (a) This Act shall be broadly construed and applied in order to fully promote its underlying purposes. If any provision of this initiative conflicts directly or indirectly with any other provisions of law, or any other statute previously enacted by the Legislature, it is the intent of the voters that such provisions shall be null and void to the extent that they are inconsistent with this initiative and are hereby repealed.

(b) No provision of this Act may be amended by the legislature except to further the purposes of that provision by a statute passed in each house by roll call vote entered in the journal, two-third of the membership concurring, or by a statute that becomes effective only when approved by the electorate. No amendment by the legislature shall be deemed to further the purposes of this Act unless it furthers the purpose of the specific provision of this Act that is being amended. In any judicial action with respect to any legislative amendment, the court shall exercise its independent judgment as to whether or not the amendment satisfies the requirements of this subsection.

(c) If any provision of this Act or the application thereof to any person or circumstances is held invalid, that invalidity shall not affect other provisions or applications of the Act that can be given effect in the absence of the invalid provision or application. To this end, the provisions of this Act are severable.

(d) In the event that this measure and another measure or measures relating to prescription drug purchasing, discounts, or price negotiation shall appear on the same statewide election ballot, the provisions of the other measure or measures shall be deemed in conflict with this measure. In the event that this measure receives a greater number of affirmative votes, the provisions of this measure shall prevail in their entirety, and the other measure or measures shall be null and void.

SA2005RF0051

SECTION 1. Title.

This Act shall be known as the "Affordable and Safe Prescription Drugs for All Californians Act"

SECTION 2. Findings and Declarations.

The People of California find and declare the following:

Prescription drugs cost 70% more in California than they do in other countries. Drug companies knowingly sell dangerous drugs.

Other countries use their buying power to negotiate prescription drug discounts. The State of California negotiates drug discounts on behalf of state workers, elected officials and the Governor. Existing laws do not allow most Californians to access similar discounts.

Therefore, the People of California declare that reform is necessary. First, all Californians shall be allowed to join a discount program to access affordable prescription drugs at local pharmacies. This purchasing program will operate on a key market principle: the bigger the buyer, the better the price. Second, unfair price gouging by drug companies will be controlled. Third, drug companies and marketers will be required to tell doctors and the public about the health risks of prescription drugs. Drug companies and marketers shall pay a fee to cover the costs of administering these new laws so that this reform will cost taxpayers nothing.

SECTION 3. Purpose and Intent.

The purpose of this Act is to provide all Californians access to affordable and safe prescription drugs.

SECTION 4. Part 9 (commencing with Section 22980) is added to Division 5 of Title 2 of the Government Code, to read:

22980. This chapter shall be known and be cited as the Affordable and Safe Prescription Drugs for All Californians Act ("Act")

Article 1. Voluntary Access to Prescription Drug Discounts

22981. Any individual, regardless of income or insurance status, shall be allowed to join a prescription drug discount program administered by the Board of Administration of the Public Employees' Retirement System ("Board").

22982. The Board shall issue a pharmacy card to each new enrollee to access prescription drug discounts at the same pharmacies and pharmacy networks available to state workers. The Board shall provide enrollees access to a mail-order pharmacy option.

22983. The Board shall establish procedures for continuous open enrollment to the discount program. Enrollment forms shall be made available on the Board's Web site, at participating pharmacies, physician offices and at various other locations deemed appropriate by the Board.

22984. The Board may require an enrollee to pay an annual fee that proportionally reflects the administrative cost of providing prescription drug discounts to the enrollee, except that no enrollee fee shall be required if licensing fees and fines collected under Article 25 of Chapter 9 of Division 2 of the Business and Professions Code provide for the full cost of the program. The annual enrollee fee shall not exceed ten dollars ($10) per year adjusted annually to reflect the rate of inflation.

22985. The Board may enter into contracts with entities offering services related to the administration of pharmacy benefits, or with an entity that negotiates price discounts, rebates or other savings on prescription drugs with prescription drug manufacturers, wholesalers, or pharmacies.

22986. (a) The Board shall inform the public about their eligibility under the Act through press releases, public services announcements, television, radio and newspaper advertisements, announcements on state websites and written materials, and other means. The Board shall coordinate outreach activities with the California Department of Aging and other state and local agencies.

(b) No outreach material shall contain the name or likeness of a prescription drug, pharmaceutical drug manufacturer, or elected official. The annual cost of these outreach activities shall not exceed $1 million. If deemed appropriate by the Board, additional outreach and advertising expenses may be approved by the legislature by a statute passed in each house by roll call vote entered in the journal, fifty percent plus one of the membership concurring. Annual outreach costs shall be paid out of the Prescription Drug Discount Fund.

22987. The Prescription Drug Discount Fund is hereby established and shall be maintained in the State Treasury to accept fees related to enrollment in the program and licensing fees and fines collected under Article 25 of Chapter 9 of Division 2 of the Business and Professions Code. Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the Board for purposes of the administration and maintenance of the pharmaceutical purchasing program.

22988. The Board may request from the state Legislature, and the Legislature shall provide, up to $5,000,000 to pay for initial startup costs associated with the implementation of this Act. Licensing fees and fines collected under Article 25 of Chapter 9 of Division 2 of the Business and Professions Code shall be used to repay monies provided to pay for initial startup costs.

22989. Enrollees shall pay the discounted price for prescription drugs negotiated by the Board at participating pharmacies. The amount to be paid for those drugs by enrollees may include a pharmacy dispensing fee of no more than three dollars and fifty cents per prescription adjusted annually to reflect the rate of inflation.

22990. Following public comment, the Board may adopt a preferred drug list. If the Board adopts a preferred drug list, the Board shall provide for periodic public review of, and consider suggested changes to, the preferred drug list.

22991. The Board may adopt all necessary rules and regulations to carry out the provisions of this Act. The Board shall have the authority reasonably necessary to carry out the powers and responsibilities expressly granted or imposed upon it under this Act.

Article 2. End Drug Company Profiteering

22995. Profiteering in prescription drugs is unlawful and is subject to the provisions of this section. The provisions of this section apply to pharmaceutical drug manufacturers.

(a) A pharmaceutical drug manufacturer engages in illegal profiteering if that manufacturer:

(1) Exacts or demands an excessive price;
(2) Exacts or demands a price or terms that lead to any unjust or unreasonable profit;
(3) Discriminates unreasonably against any person in the sale, exchange, distribution or handling of prescription drugs dispensed or delivered in the State; or
(4) Intentionally prevents, limits, lessens or restricts the sale or distribution of prescription drugs in this State in retaliation for the provisions of this chapter.

(b) The Board shall adopt, no later than six (6) months after voter approval of this measure and following public hearings, regulations determining excessive price and unjust or unreasonable profit.

(c) Each violation of this section is a civil violation for which the Attorney General or any person acting for the interests of itself, its members or the general public may obtain, in addition to other remedies, disgorgement and restitution, injunctive relief and a civil penalty in an amount of $100,000, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

SECTION 5. Safe Prescription Drugs

Article 25 (commencing with Section 4450) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

4450. (a) No person may act as a prescription drug marketer unless such person, and the pharmaceutical drug manufacturer represented by the person, has first secured a license from the Board of Pharmacy. The Board of Pharmacy shall implement this Article no later than six (6) months after voter approval of this measure.

- detail representative

(b) A person or manufacturer licensed under this Article:

(1) Shall not engage in any unfair or deceptive acts or practices.

(2) Shall disclose to a physician or any other person licensed to prescribe prescription drugs in this state, the health risks of, and results of any clinical trials regarding the health risks of, each prescription drug directly marketed to the physician or other person authorized to prescribe prescription drugs.

(c) A manufacturer licensed under this section shall disclose on the manufacturer's website the health risks of, and the results of any clinical trials regarding the health risks of, each prescription drug marketed by a licensed marketer employed by or representing the manufacturer in this state.

4451. A person or pharmaceutical drug manufacturer who violates a provision of this Article may be subject to revocation or suspension of the license granted under this Article.

4452. (a) The Board of Pharmacy shall require each licensee that is not a pharmaceutical drug manufacturer to pay an annual fee of $750.00.

(b) The Board of Pharmacy shall require a manufacturer employing or contracting for a prescription drug marketer or marketers in this state to pay an annual fee of $25,000 per manufacturer.

4453. A person other than a pharmaceutical drug manufacturer who violates a provision of Article, including a person who engages in the activities of a prescription drug marketer after his or her license has been revoked or suspended, shall be fined $5,000 by the Board of Pharmacy. A manufacturer who violates a provision of this Article shall be fined $25,000 by the Board of Pharmacy. The Attorney General or a district attorney, county council, city attorney, or city prosecutor may bring a civil action to enforce the provisions of this Article. Each unlawful act of prescription drug promotional or marketing activity shall constitute a separate violation of this Article.

4454. License fees and fines shall be deposited into the Prescription Drug Discount Fund, as defined under Section 22987 of the Government Code, to pay for costs associated with the Affordable and Safe Prescription Drugs for All Californians Act. No more than $2,000,000 of these fees and fines may be retained annually by the Board of Pharmacy to pay for necessary expenses related to the licensing and oversight of marketers and manufacturers. Additional funds to implement this section may be approved by the legislature by a statute passed in each house by a roll call vote entered in the journal, fifty percent plus one of the membership concurring.

4455. (a) The Board of Pharmacy may adopt all necessary rules and regulations to carry out the provisions of this Article. The Board of Pharmacy shall have the authority reasonably necessary to carry out the powers and responsibilities expressly granted or imposed upon it under this Article.

(b) In the event that the Board of Pharmacy ceases to exist, or its duties are subsumed by, or transferred to, another entity, the authorities and duties of this Article shall be transferred to the California Department of Health Services.

4456. For the purposes of this Article:

(a) "prescription drug marketer" or "marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician or any other person licensed to prescribe prescription drugs.

(b) "Pharmaceutical drug manufacturer" or "manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a licensed pharmacist.

(c) "prescription drug" means any of the following:
(1) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
(2) Any drug or device that, pursuant to federal or state law, may be dispensed only with a prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code.
(3) "prescription drug" does not include labeled veterinary drugs.

(d) "marketed" means any promotional or marketing activity carried out by the prescription drug marketer or pharmaceutical drug manufacturer.

(e) "Board of Pharmacy" means the California Board of Pharmacy.

(f) "clinical trial" means a systematic evidenced based research study designed to answer specific questions about new or existing prescription drugs, or new ways of using known treatments.

SECTION 6. Joint Purchasing

Section 22851 of the Government Code is amended to read:

The Board may enter into any joint purchasing arrangement with private or public entities if the arrangement does not jeopardize the system's tax status or its governmental plan status.

SECTION 7. Definitions and Technical Matters

Section 22998 and 22999 are added to Part 9 of Division 5 of Title 2 of the Government Code, to read:

22998. For the purposes of this part:
(a) "Enrollee" means any individual enrolled in the prescription drug discount program provided by the Affordable and Safe Prescription Drugs for All Californians Act.

(b) "Program" or "discount program" means the prescription drug discount program provided by the Affordable and Safe Prescription Drugs for All Californians Act.

(c) "Board" means the Board of Administration of the Public Employees' Retirement System.

(d) "pharmaceutical drug manufacturer" or "manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs. The term does not include a licensed pharmacist.

(e) "prescription drug" means any of the following:
(1) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
(2) Any drug or device that, pursuant to federal or state law, may be dispensed only with a prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code.
(3) "prescription drug" does not include labeled veterinary drugs.

22999. (a) This Act shall be broadly construed and applied in order to fully promote its underlying purposes. If any provision of this initiative conflicts directly or indirectly with any other provisions of law, or any other statute previously enacted by the Legislature, it is the intent of the voters that such provisions shall be null and void to the extent that they are inconsistent with this initiative and are hereby repealed.

(b) No provision of this Act may be amended by the legislature except to further the purposes of that provision by a statute passed in each house by roll call vote entered in the journal, two-third of the membership concurring, or by a statute that becomes effective only when approved by the electorate. No amendment by the legislature shall be deemed to further the purposes of this Act unless it furthers the purpose of the specific provision of this Act that is being amended. In any judicial action with respect to any legislative amendment, the court shall exercise its independent judgment as to whether or not the amendment satisfies the requirements of this subsection.

(c) If any provision of this Act or the application thereof to any person or circumstances is held invalid, that invalidity shall not affect other provisions or applications of the Act that can be given effect in the absence of the invalid provision or application. To this end, the provisions of this Act are severable.

(d) In the event that this measure and another measure or measures relating to prescription drug purchasing, discounts, or price negotiation shall appear on the same statewide election ballot, the provisions of the other measure or measures shall be deemed in conflict with this measure. In the event that this measure receives a greater number of affirmative votes, the provisions of this measure shall prevail in their entirety, and the other measure or measures shall be null and void.

SA2005RF0065

INITIATIVE MEASURE TO BE SUBMITTED DIRECTLY TO VOTERS

SECTION 1. FINDINGS AND DECLARATION OF PURPOSE

The People of the State of California do hereby find and declare that:

(a) Prescription drugs are an integral part to managing acute and chronic illness improving quality of life; and

(b) Prescription drugs are a convenient, cost-effective alternative to more costly medical interventions; and

(c) Increasing the affordability and access of prescription medicines will significantly improve healthcare quality and lower overall healthcare costs.

SECTION 2. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (CAL RX)

Division 112 (commencing with Section130600) is added to the Health and Safety Code, to read as follows:

DIVISION 112. CALIFORNIA STATE PHARMACYASSISTANCE PROGRAM (CAL RX)

Chapter 1. GENERAL PROVISIONS

130600. This division shall be known, and may be cited, as the California State Pharmacy Assistance Program or Cal Rx.

130601. For the purposes of this division, the following definitions shall apply:

(a) "Benchmark price" means the price for an individual drug or aggregate price for a group of drugs offered by a manufacturer equal to the lowest commercial price for the individual drug or group of drugs.

(b) "Cal Rx" means the California State Pharmacy Assistance Program.

(c) "Department" means the State Department of Health Services.

(d) "Fund" means the California State Pharmacy Assistance Program Fund.

(e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.

(f) (1) "Lowest commercial price" means the lowest purchase price for an individual drug, including all discounts, rebates, or free goods, available to any wholesale or retail commercial class of trade in California.

(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.

(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.

(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.

(g) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(h) "Manufacturers rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(i) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(j) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third–party payer program.

(k) "Recipient" means a resident that has completed an application and has been determined eligible for Cal Rx.

(l) "Resident" means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.

(m) "Third–party vendor" means a public or private entity with whom the department contracts pursuant to subdivision (b) of Section 130602, which may include a pharmacy benefit administration or pharmacy benefit management company.

130602. (a) There is hereby established the California State Pharmacy Assistance Program or Cal Rx.

(b) The department shall provide oversight of Cal Rx. To implement and administer Cal Rx, the department may contract with a third–party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi–Cal program's fiscal intermediary.

(c) Any resident may enroll in Cal Rx if determined eligible pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS

130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third–party payer.

(B) The Medi–Cal program.

(C) The children's health insurance program.

(D) The disability medical assistance program.

(E) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare.

(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:

(A) The third–party payer that paid all or part of the coverage filed for bankruptcy under the federal bankruptcy laws.

(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001), as amended.

(C) The individual is no longer eligible for the Medi–Cal program, children's health insurance program, or disability medical assistance program.

(b) Application and an annual reapplication for Cal Rx shall be made pursuant to subdivision (d) of Section 130606. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

130606. (a) The department or third–party vendor shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx.

(b) The application, at a minimum, shall do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable under penalty of perjury.

(4) Specify that the application and annual reapplication fee due upon submission of the applicable form is fifteen dollars ($15).

(c) In assessing the income requirement for Cal Rx eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx, through a Web site or call center staffed by trained operators approved by the department, or through the third–party vendor. A pharmacy, physician office, clinic, or third–party vendor completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a recipient.

(e) The department or third–party vendor shall utilize a secure electronic application process that can be used by a pharmacy, physician office, or clinic, by a Web site, by a call center staffed by trained operators, or through the third–party vendor to enroll applicants in Cal Rx.

(f) During normal hours, the department or third–party vendor shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department or third–party vendor shall mail the recipient an identification card no later than four days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department or third–party vendor may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to Cal Rx.

130607. (a) The department or third–party vendor shall attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.

(b) (1) Private discount drug programs may require an applicant to provide additional information, beyond that required by Cal Rx, to determine the applicant's eligibility for discount drug programs.

(2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, private discount drug programs in order to participate in Cal Rx.

(3) Notwithstanding paragraph (2), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.

(c) For those drugs available pursuant to subdivision (a), the department or third–party vendor shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private discount drug programs.

(d) The recipient identification card issued pursuant to subdivision (g) of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130615. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about Cal Rx and private drug discount programs available through the single point of entry as specified in subdivisions (a) and (d) of Section 130607. No outreach material shall contain the name or likeness of a drug. The name of the organization sponsoring the material pursuant to subdivision (b) may appear on the material once and in a font no larger than 10 point.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx. Neither Section 11005 of the Government Code, nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans. Outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.

(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

130616. (a) Any pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of the Business and Professions Code may participate in Cal Rx.

(b) Any manufacturer, as defined in subdivision (g) of Section 130601, may participate in Cal Rx.

130617. (a) This division shall apply only to prescription drugs dispensed to noninpatient recipients.

(b) The amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate pursuant to subdivision (c), plus a dispensing fee that shall be negotiated as part of the rate pursuant to subdivision (c), less the applicable manufacturers rebate.

(c) The department or third–party vendor may contract with participating pharmacies for a rate other than the pharmacist's usual and customary rate. However, the department must approve the contracted rate of a third–party vendor.

(d) The department or third–party vendor shall provide a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of subdivision (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8(g)).

(e) The department or third–party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received.

(f) The department or third–party vendor shall develop a program to prevent the occurrence of fraud in Cal Rx.

(g) The department or third–party vendor shall develop a mechanism for recipients to report problems or complaints regarding Cal Rx.

130618. (a) In order to secure the discount required pursuant to subdivisions (b) and (c) of Section 130617, the department or third–party vendor shall attempt to negotiate drug rebate agreements for Cal Rx with drug manufacturers.

(b) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

(8) Permit a manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a recipient's health information.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available within Cal Rx.

(d) The entire amount of the drug rebates negotiated pursuant to this section shall go to reducing the cost to Cal Rx recipients of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.

(e) The department or third–party vendor may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

(f) Drug rebate contracts negotiated by the third–party vendor shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or Cal Rx recipients.

(g) The third–party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to subdivision (e) of Section 130617. The department shall develop a system to prevent diversion of funds collected by the third–party vendor.

130619. (a) The department or third–party vendor shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A Summary of the problems or complaints reported regarding Cal Rx.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130620. (a) The department or third–party vendor shall deposit all payments received pursuant to Section 130618 into the California State Pharmacy Assistance Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, moneys in the fund are hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering Cal Rx. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

130621. The department may hire any staff needed for the implementation and oversight of Cal Rx.

130622. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) and that discounts provided under the program are exempt from Medicaid best price requirements.

130623. (a) Contracts and change orders entered into pursuant to this division and any project or systems development notice shall be exempt from all of the following:

(1) The competitive bidding requirements of State Administrative Manual Management Memo 03–10.

(2) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(3) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.

(b) Change orders entered into pursuant to this division shall not require a contract amendment.

130624. The department may terminate Cal Rx if the department makes any one of the following determinations:

(a) That there are insufficient discounts to participants to make Cal Rx viable.

(b) That there are an insufficient number of applicants for Cal Rx.

(c) That the department is unable to find a responsible third–party vendor to administer Cal Rx.

130625. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division

in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action.

SECTION 3: GENERAL PROVISIONS

(a) Conflicting Measures.

(1) This measure is intended to be comprehensive. It is the intent of the People that in the event that this measure and another initiative measure or measures relating to the same subject shall appear on the same statewide election ballot, the provisions of the other measure or measures shall be deemed to be in conflict with this measure. In the event that this measure shall receive a greater number of affirmative votes, the provisions of this measure shall prevail in their entirety, and all provisions of the other measure or measures shall be null and void.

(2) If this measure is approved by voters but superseded by law by any other conflicting ballot measure approved by the voters at the same election, and the conflicting ballot measure is later held invalid, this measure shall be self-executing and given full force of law.

(b) Severability: The provisions of this chapter are severable. If any provision of this chapter or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(c) Amendment: The provisions of this Act may be amended by a statute that is passed by a vote of two-thirds of the membership of each house of the Legislature and signed by the Governor. All amendments to this Act shall be to further the Act and shall be consistent with its purposes.

Legislation and Regulation Committee
Strategic Plan Update for April 2005

Goal 3:	**Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.**
Outcome:	**Improve the health and safety of Californians.**

Objective 3.1:	**Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.**
Measure:	**100 percent successful enactment of promoted legislative changes**
Tasks:	1. Secure extension of board's sunset date. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 3. Sponsor legislation to add enforcement options for non-compliance issues. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. **Advocacy: AB 1196, SB 151, SB 175, SB 361, SB 490, SB 545, SB 774** **Technical Assistance: AB 262, AB 746, AB 1196, AB 1957, AB 2125, SB 151, SB 175, SB 292, SB 361, SB 490, SB 545, SB 774, SB 907, SB 1149** 6. Sponsor clean-up language to B & P Code section 4312. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 7. Sponsor public meetings 4 times a year to solicit comments on areas needing legislative changes. **Public meetings held on March 27, 2003 and September 11, 2003.** **Public meeting scheduled for March 30, 2004.** 8. Sponsor legislation to strengthen consumer protections in wholesale transactions. **January 2004 - Board approved draft legislation.** **February 2004 – SB 1307 introduced.** 9. Sponsor legislation to address licensing issues related to the UC Davis Veterinary Medical Teaching Hospital.

	July 2003 – Board approves draft language.

Objective 3.2:	**Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.**
Measure:	**Percentage successful enactment of promoted regulatory changes**
Tasks:	1. Strengthen standards for compounding sterile injectable drug products. **In process. Rulemaking approved by board in October 2003.** **February 2004 – Rulemaking Submitted to OAL** 2. Authorize the executive officer the authority to issue citations and fines. **Completed. Regulation effective October 11, 2003.** 3. Eliminate the clerk typist ratio. **September 2003 - Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously. **September 2003 - Informational hearing held.** **February 2004 - Rulemaking Notice Published.** 5. Update pharmacy self-assessment form. 6. Allow central filling by hospital pharmacies. **September 2003 - Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. **September 2003 - Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 8. Modify patient notification provision of the quality assurance regulation to require notification only if the error results in the medication being administerd to the patient or a clinically significant delay in therapy. **July 2003 – Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 9. Require pharmacies using a common electronic file to adopt policies to ensure confidentiality of patient information. **September 2003 – Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 10. Update pharmacy technician regulations to conform to SB 361. **September 2003 – Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 11. Update pharmacist licensure regulations to conform to SB 361.

	September 2003 – Informational hearing held. **February 2004 – Rulemaking Notice Published.** 12. Complete a Section 100 filing to clean up regulations in conformity with recent legislation.

Objective 3.3: **Measure:**	**Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.** **Number of areas of pharmacy law reviewed**
Tasks:	1. Evaluate electronic prescribing laws involving controlled substances. 2. Evaluate the prescribing and dispensing of veterinary drugs. **Completed – Chapter 250, Statutes of 2003 (SB 175)** 3. Evaluate group dispensing by prescribers. **August 2003 - Draft legislation developed in concert with the Medical Board. Awaiting board action.** 4. Evaluate pharmacist intern statutes and regulations. **December 2003 – Draft legislation and regulations prepared and presented to the Licensing Committee.** **January 2004 – Draft legislation and regulations approved by the board.** **February 2004 – Rulemaking noticed on approved regulations.** **March 2004 – Statutory provisions introduced in SB 1913.**